



**Promoting safer chemical use:  
towards better regulation of chemicals in Australia**

FINAL REPORT AND RECOMMENDATIONS December 2006

# FINAL REPORT

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## EXECUTIVE SUMMARY

This is the Final Report and Recommendations of the Existing Chemicals Program Review Steering Committee (RSC) to the Director, NICNAS for the Existing Chemicals Assessment Program Review (Review) initiative. The RSC was charged to oversee the Review to ensure that the process was consistent with the principles and protocol of the NICNAS Community Engagement Charter.

The RSC is of the view that the recommendations offer stakeholders a more flexible and transparent Existing Chemicals Assessment Program (EC Program) that is more responsive to the needs of all stakeholders. The RSC has identified five key reform drivers, consisting of 23 recommendations that address issues ranging from communication and engagement through to legislative reach and control powers. It is expected that these recommendations will enhance regulatory efficiency and lead to more effective outcomes for the community, industry and government. The recommended reforms will provide greater access to information about more chemicals, enhance relationships between stakeholders, including government and lead to improvements in the safe and sustainable use of chemicals in Australia.

The overall success of delivering significant reforms to the EC Program is dependent on the delivery of the proposed reform elements as an integrated package. This will ensure full community confidence in NICNAS and its EC Program while enabling the benefits of enhanced efficiency and effectiveness to flow on to all stakeholders. Throughout the review, the process took a balanced approach ensuring that concerns of community, industry and government have been integrated into its work.

The RSC notes that the reforms are consistent with international trends towards best practice regulation for existing industrial chemicals. Indeed, a number of the reforms are similar to those adopted by other international regulatory bodies. The reform proposals therefore present opportunities for greater international cooperation and harmonisation on chemical safety issues.

The RSC commends these recommendations to the Director, seeking agreement for this package of reforms so as to enhance the efficiency and effectiveness of the scheme. The RSC notes that further development and consultation of some elements of the reform proposals will be required prior to implementation. In the development and implementation of each recommendation, full consultation with the community, industry and relevant government bodies should occur.

### **Summary of recommendations**

Twenty-three recommendations are described in this report. The recommendations have been grouped into five key reform drivers as follows:

1. Better engagement and communication
2. Enhancing mechanisms to identify chemicals of concern: new screening processes
3. Improving efficiency
4. Targeted assessments
5. Increasing legislative reach: enhanced control powers

Some recommendations can be directly implemented by NICNAS, such as the development of guidance documents and bulletins, once accepted. However, other Recommendations will require further development and stakeholder engagement to ensure effective implementation, with a few designated for progression via other mechanisms.

All recommendations have also been categorised into three types, namely:

- I** innovative elements to the EC Program
- M** modified elements of the current program
- C** consequential activities that maintain regulatory confidence.

### Summary guide to recommendations

The following is an abridged summary of the recommendations; they can be found at the page number given. Each has also been categorised according to the above three recommendation types.

Area	Recommendation number	Page
Refer proposals for an extension of legislative reach to the Ministerial Taskforce on Chemicals and Plastics	1	4
Implement recommendations in partnership with industry, community, and government	2	7
<i>Better engagement and communication</i>		
Promote community awareness of, education about, and participation in, the Existing Chemicals Assessment Program (EC Program)	<b>M</b> 3.1	10
Publish a 'Who's Who Guide' for industrial chemicals safety assessment and management	<b>C</b> <b>M</b> 3.2	11
Develop a current awareness bulletin on international chemical safety information and issues relevant to the program	<b>C</b> 3.3	11
<i>Enhancing mechanisms to identify chemicals of concern: new screening processes</i>		
Develop an overall framework for screening of chemicals of concern	<b>I</b> 4.1	13
Screen AICS listed chemicals for hazard and/or risk indicators elements	<b>I</b> 4.2	13
Examine the feasibility of a nationally co-ordinated system of surveillance monitoring and post market reporting	<b>I</b> 4.3	15
Develop a framework to identify the circumstances under which downstream use information is sought as being necessary for prioritisation	<b>I</b> 4.4	17

Area	Recommendation number	Page
<i>Improving efficiency</i>		
Develop, modify and publish process to filter out and redirect non NICNAS matters and determine the level of response and/or assessment required	M 5.1	19
Develop scientifically based criteria for prioritisation of chemicals for assessment	M 5.2	19
Publish the prioritisation process and decisions	C 5.3	19
Streamline the secondary notification process for existing chemicals originally assessed as new chemicals	M 5.4	19
Explore with States and Territories improved processes for co-ordination and co-operation including under its MOU group	M 5.5	20
Continue to participate in chemicals management forums to ensure harmonised and streamlined regulation of industrial chemicals at the national level	M 5.6	20
Explore an extension of the Bilateral Agreement with Canada to include existing chemicals	I 5.7	21
Explore the development of similar arrangements with other major trading countries	I 5.8	21
Increase and broaden consultation with stakeholders during the assessment process and before recommendations are finalised	C 5.9	22
Recommendations are action statements that are evidence based, specific to the needs identified, achievable, and practical and be directed to the most appropriate body for implementation	C 5.10	23
Refer the proposal to investigate the barriers to effective implementation of NICNAS recommendations to Ministerial Taskforce on Chemicals and Plastics for their consideration	5.11	24
<i>Targeted assessments</i>		
Develop new types of assessment products based on intended output and purposes	I 6.1	26-7
Develop information requirements for each new assessment type	M 6.2	28
<i>Increasing the legislative reach: enhanced control powers</i>		
Refer the range of issues related to the ban, severe restriction and/or the control of certain chemicals to Ministerial Taskforce on Chemicals and Plastics	7	31

## GLOSSARY OF TERMS AND ABBREVIATIONS USED IN THIS REVIEW

AICS	Australian Inventory of Chemical Substances
ASCC	Australian Safety and Compensation Council (Australian Government) – formerly NOHSC: National Occupational Health and Safety Commission
Banks Report	Rethinking Regulation Report of The Taskforce on Reducing Regulatory Burdens on Business, Report to the Prime Minister and the Treasurer
CICADS	IPCS program for Concise International Chemical Assessment Documents
CMR	Carcinogens, mutagens and reproductive toxicants
COAG	Council of Australian Governments
DEH	Department of Environment and Heritage (Australian Government)
DEWR	Department of Employment and Workplace Relations (Australian Government)
Downstream users	Organisations other than those that only import and manufacture, who use industrial chemicals in the course of their industrial or commercial activities – includes formulators and suppliers of industrial chemicals and chemical products, but not consumers
EPHC	Environment Protection and Heritage Council
EU	European Union
Existing chemicals	Chemicals that are on the Australian Inventory of Chemical Substances (AICS) including those already in use in Australia
HSIS	Hazardous Substances Information System, listing about 3000 industrial chemicals classified as hazardous in the workplace – many have already been assessed internationally
HVICL	High Volume Industrial Chemicals List (NICNAS) list of 250 chemicals introduced at > 1000 tonnes per year; with another 450 chemicals introduced at > 100 tonnes per year
IC(NA) Act or the Act	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i>
IPCS	International Program on Chemical Safety
MOU	Memorandum of Understanding
MSDS	Material Safety Data Sheets

NChEM	National Chemicals Environmental Management. A program developed by the Chemicals Working Group set up by the Environment Protection and Heritage Council of Ministers (EPHC) aimed at ensuring that environmental considerations are fully integrated into Australian chemicals management systems, to reduce fragmentation and to improve the streamlining of regulation and co-ordination of efforts across the various levels of government.
NDPSC	National Drugs and Poisons Scheduling Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (within the Australian Government Department of Health and Ageing)
NPI	National Pollutant Inventory
OASCC	Office of the Australian Safety and Compensation Council - ASCC ( <i>see above</i> )
OCS	Office of Chemical Safety (Australian Government)
OECD	Organisation for Economic Cooperation and Development
OHS	Occupational Health and Safety
PBT	Persistent, bioaccumulative and toxic
PEC	Priority Existing Chemical (NICNAS)
PIC	(Rotterdam Convention on the) Prior Informed Consent procedures for certain hazardous chemicals and pesticides in international trade
POP	(Stockholm Convention on) Persistent Organic Pollutants
REACH	Registration, Evaluation and Authorisation of CHemicals – the proposed EU regulatory framework
RSC	Review Steering Committee
SIDS	OECD program for Screening Information Data Set
Stakeholders	All those affected by a program such as workers, government and industrial sectors and community interest groups
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
UNCED	United Nations Conference on Environment and Development

## ACKNOWLEDGEMENTS

The Existing Chemicals Review Steering Committee (RSC) would like to acknowledge the contributions of the many individuals and representatives from both private and public sector organisations who took the time to meet with the RSC, attend public forums and provide submissions to the RSC. The findings and final recommendations in this report represent their thoughts and recommendations for improving the Existing Chemicals Assessment Program.

The RSC is also grateful to members of expert working parties whose work formed a solid foundation of the proposals outlined in the discussion paper: *Promoting safe chemical use: towards better regulation of chemicals in Australia*, published April 2006.

Grateful thanks are also due to the six members of the NICNAS Community Engagement Forum who contributed their time and expertise to the guidance, publicity and facilitation of the public forums.

Finally, the RSC would like to record its appreciation of the efforts of NICNAS staff who supported the work of the RSC and the overall Review process.

## CHAPTER 1: SETTING THE SCENE

### Chemicals in Australia

Like societies in other developed nations of the world, Australian society relies on the use of chemicals in its food, medicines, and agriculture and in our industrial and consumer products. We use chemicals every day and are exposed to them to the extent that they have become an integral part of our lives. For example, we use industrial chemicals in our cleaning products, cosmetics and paints. We may be exposed through direct or indirect means, for example via residues in food, water and air.

The chemicals and plastics industries in Australia are a diverse sector comprising base and feedstock products, speciality and refined chemicals, intermediate goods and components as well as finished products. Seventy percent of the output of these industries is used as essential inputs to other manufacturing and industrial sectors (automotive, building and construction, packaging, medical, agriculture and mineral processing). In 2002-03 the industry reported annual turnover of \$27 billion or 9% of total Australian manufacturing, and employed 81,000 people or over 8% of the total manufacturing industry workforce and added over \$8 billion in value, about 9% of total value added by manufacturing. The sector has annual imports of over \$11 billion. Australians spend some \$4.1 billion on cosmetics, perfumes and toiletries each year and Australia accounts for 1.2% of the world market.

To aid in the safe and sustainable use of chemicals in Australia, it is important that the health and environmental effects of chemicals are evaluated and that sufficient information about them is widely available.

### Role and functions of NICNAS

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) aids in the protection of workers, the public and the environment from the harmful effects of a wide range of industrial chemicals including plastics, paints, inks, surface coatings, cosmetics and other consumer chemicals. NICNAS was established in July 1990 under Australian Government legislation: the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act).

The Scheme ensures the safe use of chemicals by making risk assessment and safety information on chemicals and their potential occupational health and safety (OHS), public health and/or environmental risks widely available to workers, the public, industry and other state, territory and Australian Government agencies. Further, NICNAS scientific risk assessments support the wide range of chemicals management legislation aimed at protecting human health and the environment from the adverse effects of chemicals.

NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used or released to the environment. NICNAS also assesses those chemicals that are already in use in Australia (known as 'existing chemicals') on a priority basis in response to specific concerns about potential health and/or environmental effects.

In conducting its assessments, NICNAS takes into account the life cycle of each chemical and its impact on health and the environment at each stage. Exposure to the chemical via direct and indirect sources, for example through contact with water and air, is taken into account. The supply chain from introduction to end-use and disposal of the chemical can be listed as follows:

- Introduction (importation or manufacture)
- Distribution
- Formulation of products
- Supply to customers
- End-use by workers and/or the public
- Disposal, eg. of waste
- Export.

## **Engagement**

An important aspect to good regulation is the ongoing periodic examination of regulatory processes and practices to assess their effectiveness and identify opportunities for improving them. In doing this, an effective engagement with all stakeholders will ensure that the regulation remains ‘fit for purpose’ and will promote acceptance of and compliance with the regulation.

NICNAS has a strong track record of developing innovative reforms to its regulatory framework, which has seen the development and implementation of the concept of Low Regulatory Concern Chemicals (LRCC), the refocussing of cosmetic regulations to simplify industry compliance and other streamlining activities aimed at reducing administrative costs and reducing duplication. These reform activities also included a balanced package of actions aimed at reducing regulatory burden to industry while enhancing the availability of chemical safety information to the public. These reforms have resulted in safer and sustainable chemical use.

The success of these recent regulatory reform activities is due in part to the processes developed to undertake them. For example, the reform program of the recent Chemicals and Plastics Action Agenda provided a major stimulus for government/industry/community partnerships in identifying regulatory issues and finding innovative solutions agreeable to all parties. This process established the need for the regulator and its stakeholders to be open to new concepts and approaches within the Government’s regulatory policies. The value in this approach is that it triggers a shift in regulatory processes towards continuous improvement and innovation.

The importance of effective engagement or consultation with all affected parties lies in the fact that all views are fed into regulatory reform considerations and information perspectives that might not be otherwise available can be captured. This process can assist in limiting the risk of any unintended consequences of regulatory intervention while ensuring the regulatory output achieves its intended purposes.

One of the enduring outcomes of the LRCC reforms was the commitment by NICNAS to operate in partnership with stakeholders. This complements the formal consultation mechanisms with industry, community and governments. Further, the *NICNAS Community Engagement Charter* sets out the principles and protocols of best practice engagement within which this review has been conducted.

## International trends

The identification and management of risks posed by existing chemicals is a primary focus of most national, regional and international chemicals safety programs. An analysis of the existing chemicals programs of a number of countries relevant to global trade in chemicals and plastics is presented at [Appendix 1](#).

It is noted that globally, governments and international agencies alike, have acknowledged the shortcomings in assessment and management of existing chemicals. The key issue identified is that only a limited number of existing chemicals have been reviewed due to the resource intensive nature of current assessment approaches. This has resulted in there being concerns over the insufficient know-ledge about human health and environmental risks for many of the chemicals on the market.

This issue has seen governments begin to review their existing chemicals programs. Initiatives currently being considered in the EU under the REACH scheme to address these concerns include refocusing assessment programs to screen for priority issues, increased safety testing and enhanced tools to evaluate chemical exposure and refocusing on specialised issues, such as susceptible populations and newly recognised health and environmental effects.

The refocus of overseas assessment programs such as that occurring in the EU will see a rapid growth of available information on existing chemicals, globally. The challenge will be how best to use this information to maximise efficiencies, reduce duplication and provide chemical safety information in a form that will be useful to stakeholders.

## Need for the review

The last review of NICNAS's Existing Chemicals Assessment Program (EC Program) occurred in 1997, as part of the introduction of full cost recovery by the Government. A number of new elements were introduced into the EC Program. Significantly, the cost recovery arrangement for the EC program was changed to be more efficient and correct the market distortions that the PEC fees system has created. The introduction of a NICNAS Registration scheme across the broader industry base removed the disincentive for the industry to comply and facilitated an improved process for information exchange.

At the same time, the review identified the need for improved performance in the output of assessments in the EC Program. To this effect the Government announced that a performance target of 10 priority existing chemicals (PECs) assessments and 40-50 other assessments be completed in each three-year cycle. The revised EC Program commenced April 1998 with a scheduled internal review to occur at the end of the first cycle. This review timetable was later revised so as to take account of the major resetting of the EU existing chemicals regulations (now known as REACH). This decision reflected the concern that revising the NICNAS EC Program in isolation of regulatory changes occurring in major trading partners could reduce the ability to utilise overseas assessments within the NICNAS program as well as impact on harmonisation activities.

Notwithstanding this – and as identified internationally – a large proportion of the industrial chemicals in use remain unassessed or not fully assessed for their health and environmental risks. The Australian Inventory of Chemical Substances (AICS) lists 38,000 chemicals potentially in use, and most 'grandfathered' onto AICS at the time of the establishment of NICNAS. The challenge remains for NICNAS to identify and prioritise these chemicals in use in Australia for assessment for the protection of the Australian people and the environment.

## The policy framework

As this is a review of internal processes, NICNAS's regulatory policy framework governed this review. Thus options identified as part of this review took into account the following policy determinants as a given:

- NICNAS operates on full cost-recovery
- The regulatory approach is chemical entity based
- The scope of the regulation covers occupational health and safety, public health and environmental protection
- NICNAS does not register chemical products
- The regulatory approach is risk-based with the level of resource input commensurate with the risks posed
- Chemicals are reviewed on a priority basis
- Risk assessment and management decisions encompasses the Precautionary Principle as defined in *Principle 15 of Agenda 21 of the 1992 United Nations Conference on Environment and Development (UNCED)* which states:

*... In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

In addition, it is expected that, consistent with Government policy, the ongoing cost of any new elements to be introduced within the EC Program will be, as a general rule, offset through efficiency savings.

It is noted that COAG has announced, as part of a new wave of reform commitment in response to the Banks Report, the establishment of a Ministerial Taskforce on Chemicals and Plastics to address with priority a number of issues in the sector including a national chemicals policy framework. While the review of the EC Program is seen as internal to NICNAS, because of the open process in identifying issues, it is recognised that there may be broader issues raised during the review and consultation process.

### Recommendation 1

That any proposals for reform to the NICNAS EC Program that are outside the policy mandate of NICNAS be referred to the COAG Ministerial Taskforce on Chemicals and Plastics for broader consideration.

## CHAPTER 2: ABOUT THE EXISTING CHEMICALS ASSESSMENT PROGRAM AND THE REVIEW PROCESS

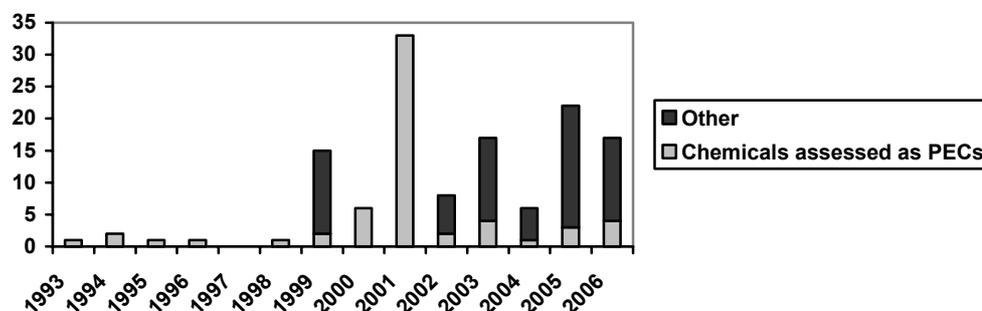
### About the Existing Chemicals Assessment Program

The most well known activity of the EC Program is the assessment of chemicals known as PECs. PEC assessments are legislated under the IC(NA) Act, and have legislated timeframes and consultation and appeal provisions.

Prior to 1997-98, all three aspects of the NICNAS legislative cover (ie. occupational health and safety - OHS, public health and environmental effects) had to be considered in assessments for all chemicals declared as PECs. This had to occur even in situations where the concerns were restricted only to one or two of these areas. This meant the assessment approach was unnecessarily complex and inefficient. This led to legislative changes to the IC(NA) Act in 1997-8 that expanded the type of PEC assessments to allow for group/class assessments as well as focussed assessments (eg. public health only). Details of the current EC Program are given at [Appendix 2](#).

### Performance output

The reforms to the program in 1997-8 enabled the quicker generation and dissemination to the Australian community of chemical safety information on chemicals of priority concern. The output of the EC Program for the period 1992-2006 is shown in the figure below.



NICNAS has exceeded the three-year assessment targets over the past two cycles. Importantly, the shift to more focussed assessment has seen, in addition to maintaining PEC assessment output, an increased level of assessments addressing specific concerns in a responsive manner. Thus there is an established level of effectiveness and efficiency within the current program. The review seeks to enhance this performance record.

### Continuous improvement

Notwithstanding the improvements delivered by past reform activities of the EC Program, the international activity in existing chemicals safety assessment meant that it was opportune to reconsider the approach NICNAS takes to its EC Program. This complemented the fact that periodic internal reviews are integral to the ongoing ability of the regulator to deal with scientific advances, technological developments, emerging issues

internationally and the growing demand for chemical safety information by the community.

To this end, the EC Program was examined against emerging national and international trends to ensure that it continues to be responsive and flexible to meet the national needs and priorities of NICNAS's stakeholders, while ensuring efficient and effective utilisation of resources.

### **What to review**

Prior to the formation of a formal review mechanism, NICNAS consulted about 20 key stakeholders including industry, government agencies, non-government organisations that had been involved in the LRCC program and a number of clinicians with an interest in worker safety. From this process, NICNAS prepared a list of suggested issues and areas that should be included in any formal review of the EC Program. To further develop the identification of issues, NICNAS held a Brainstorming Workshop in August 2003 (see [Appendix 3](#) for the report of this workshop).

From this work, it was identified that one of the major barriers for the assessment and risk management of existing chemicals is identifying which chemicals are actually used in Australia, in what volume and for what uses. Finding this information on an individual chemical basis so far has proved to be resource intensive for NICNAS. This begs the question as to whether there are more efficient ways to collect this information, as well as how to identify what information is actually needed to meet the public's need to know about chemicals to which they are exposed.

Further, the need to be able to prioritise chemical assessment is based on the risks they pose; to assess chemicals in a more rapid and responsive way and to see a greater impact on chemical safety arising from the assessment effort. NICNAS also needed to find better ways of sharing and integrating information relevant for chemicals management and ensuring its accessibility, dissemination and usefulness for different users.

### **Scope of the review**

The review has considered the current EC Program in terms of its:

- efficiency and effectiveness
- flexibility and responsiveness to stakeholder needs, and
- harmonisation with comparable schemes and the need to reflect international trends in best practice chemicals regulation.

In doing this, the review has sought mechanisms to: better determine national priorities for assessment of existing industrial chemicals, better utilise relevant overseas testing and assessment reports, and better address the needs of the community and industry regarding access to scientifically sound information on industrial chemical hazards and risks.

### **Expected benefits of the review**

This review has been undertaken to identify structural and process reforms to ensure that the regulatory system continues to be flexible, responsive to emerging issues and concerns, is simple to comply with and delivers its intended outcome of safe and sustainable use of chemicals. The anticipated benefits expected for each stakeholder group are as follows:

*For the Government* – nationally significant chemical issues are effectively and promptly addressed, more efficient use of existing resources, increase in the utility of public

information on a larger number of chemicals in use, enhanced relationships with stakeholders, enhanced implementation of controls, improved use of overseas information and reduction in duplication of assessment effort.

*For the community* – improved access to better targeted chemical safety information, increased information on a larger number of chemicals in use, safer use of chemicals, better health and environmental protection outcomes, and more informed community to be able to better engage in chemicals regulation.

*For industry* – better utilisation of cost-recovered funds, reduced complexity of processes (and easier compliance with) the EC Program, improved clarity of the legislative framework, enhanced regulatory system with enhanced consumer confidence in chemical products, improved access to chemical safety information to support their compliance obligations, increased knowledge about chemicals available for use.

### How the review was conducted

NICNAS carried out the review consistent with the principles and protocols of its Community Engagement Charter. This mandates a commitment to open processes carried out in partnership with industry, community and government. To oversee this process, an EC Program Review Steering Committee (RSC) was established.

#### Recommendation 2

That the strategy for the implementation of accepted review recommendations be carried out in partnership with industry, community and government using the principles and protocols of the NICNAS Community Engagement Charter.

The RSC comprised equal representation from the community, industry, and government to work with NICNAS in overseeing this Review. An independent Chair was appointed to the RSC. Membership of the RSC, its technical work groups and the terms of reference are detailed in [Appendix 4](#).

The RSC using the issues identified in earlier ‘brainstorming meetings’ developed a framework under which the Review would be considered.

Given the scale and technical nature of the NICNAS EC Program, the RSC established a series of technical working groups that focussed on three broad areas:

- Working Group 1:*      INPUTS - detection and identification of chemical hazards, risks and concerns.
- Working Group 2:*      Assessment PROCESSES - to address detected / identified hazards, risks and concerns.
- Working Group 3:*      OUTPUTS - development of a regulatory framework to ensure best practice regulation of existing chemicals, including national implementation of NICNAS guidance and advice on safe use, elimination and risk reduction.

Each technical working group comprised equal representation from community, industry and government (see [Appendix 4](#) for details).

As the review developed, and prior to the RSC finalising a public discussion paper, focus group consultations were undertaken in November 2005 to test a suggested 'New Model for the EC Program'.

There was general support for the improvement framework. The feedback from these meetings provided the RSC with valuable input to allow it to further refine the Model and finalise a Public Discussion Paper *Promoting safer chemical use: towards better regulation of chemicals in Australia* (see [Appendix 5](#) for the text of the Executive Summary and Proposals) which was released for public comment in April 2006.

To facilitate public engagement and encourage wide consideration of the Discussion Paper, the NICNAS Community Engagement Forum assisted NICNAS in hosting a total of 21 public engagement forums held in eleven locations around Australia, comprising all capital cities and three regional centres (see [Appendix 4](#) for details).

There was a strong response to the forums with a total of 170 people attending. Attendee affiliations comprised 35% community, 20% industry, 33% government and 12% other organisations, eg. educational institutions. This is the largest public participation in NICNAS reform activities to date and reflects both the level of interest in the EC Program and chemicals in general, as well as the effectiveness of the engagement strategy.

At the end of the public comment period on the Discussion Paper, 56 written submissions were received from individuals and organisations. The majority of these (42 or 75%) were from the community, with seven (12.5%) from government, four (7.1%) from industry (associations and peak bodies) and three (5.4%) from other organisations. All written submissions as well as a summary of the comments received during the public forums were placed on the NICNAS website. A summary of the public comments is given at [Appendix 6](#).

The Discussion Paper contained 20 proposals for improvement to the EC Program, which drew wide interest and comment. In general, the need for an EC Program was confirmed and supported, as was the scope of its coverage in relation to human health and safety.

Submissions received can be summarised into five major areas for consideration:

**Better engagement and communication**

**Enhancing mechanisms to identify chemicals of concern:  
new screening processes**

**Improving efficiency** – redesigning processes, enhancing relationships

**Broadening assessment options**

**Expanded legislative reach: enhanced control powers**

These broad areas of consideration for improvement, along with the findings from discussion and public comment are presented in detail in Chapters 3, 4, 5, 6 and 7.

Quotations have been provided where discussion of the proposals proved to be controversial (eg. where full support, rejection or a call for caution in progressing a proposal was suggested).

A list of additional issues identified during the course of the Review is provided at [Appendix 7](#).

## CHAPTER 3: BETTER ENGAGEMENT AND COMMUNICATION

### Background

NICNAS communicates with many and varied stakeholders through its registration, assessment, consultation and general service activities. While NICNAS communication mechanisms are generally regarded as sound, feedback has identified that many stakeholders have insufficient knowledge about NICNAS and, in particular, the EC Program. To ensure a successful EC Program NICNAS must be able to identify concerns of all stakeholders and respond in an appropriate manner. Hence it is vital that an effective communication flow between NICNAS and its stakeholders and the public is in place.

Currently NICNAS's main communication mechanisms for providing information on chemical safety information and regulatory obligations and requirements via the NICNAS website. The web has been the basis of developing a one-stop-shop for information and regulatory needs of stakeholders and has seen major redevelopment over recent years linking internal tracking databases and information management systems with external communication facilities. The web has proved to be an effective portal for information dissemination with some 15,440,000 hits and 976,342 visitor sessions being recorded for 2005-06.

Other strategies employed by NICNAS to ensure good communication processes include: general enquiries 1800 number and generic e-mail [info@nicnas.gov.au](mailto:info@nicnas.gov.au) facilities; media alerts and routine media monitoring; internal current awareness service – monitoring of chemical issues globally; advertising (national media, trade journals etc), newsletters (eg. *NICNAS Matters*); and awareness raising through training and site visits. Further, NICNAS details its performance in handling enquiries in its Service Charter and in 2005-06, successfully handled 5,341 phone and 2,394 written enquiries within performance timeframes.

These activities are complemented by formal consultative mechanisms such as the Industry Government Consultative Committee (IGCC), the States/Territories Memorandum of Understanding (MOU) Group, Community Engagement Forum (CEF) and linkages to other government agencies (eg. DEH CLEAN network for environmental policy and ASCC for OHS policy).

While NICNAS has committed to the principles and protocols of its Community Engagement Charter, it is fair to say that the program processes were developed some years ago and have not been revised taking into consideration the new Community Engagement Charter.

#### *Findings:*

The suggestions for improving communications between NICNAS and stakeholders about the EC Program (*Proposal 1*<sup>1</sup>) were generally supported by industry, government and community, both at public forums and in written submissions (see [Appendix 6](#) for

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<sup>1</sup> All twenty proposals from the *Promoting Safer Chemical Use* discussion paper of April 2006 are reproduced at [Appendix 5](#) (pages 66-70) of this report.

details). Altogether, 56 parties made submissions to the Review and these are listed at [Appendix 8](#).

The review identified the need to enhance the channels of communication to and from NICNAS, and the remove any current communication barriers. Improving the communication processes available will benefit all stakeholders, particularly those with least regular contact with NICNAS (ie. beyond the regulated industry itself of importers and manufacturers to a broader industry base, workers, and the community). Engagement programs must be targeted to need, be well coordinated to ensure that the right audiences are being targeted and that appropriate outcomes are realised. It is expected that greater confidence in the program would result from these activities.

The proposal to increase the frequency of public call for nominations of existing chemicals for assessment on the EC Program (*Proposal 2*) was generally supported at the public Forums and in written submissions noting the blast call for nomination was in 1999.

There was general support for a nomination frequency of two years, noting the need to manage cost-effectively the scale of chemical assessments that may be sought through this process.

The need to ensure stakeholder awareness of such processes so as to achieve effective engagement was highlighted. Support is noted for retaining the ability for ‘unscheduled’ nomination so that chemicals of immediate concern can be addressed in a responsive manner. All nominated chemicals would be fed into an enhanced screening and prioritisation process for the appropriate level of assessment.

### **Recommendation 3.1**

That NICNAS promote community awareness of, education about, and participation in, the Existing Chemicals Assessment Program (EC Program) through:

- The development and publication of a layperson’s guide to the EC Program (including an information flow and process diagram of the program)
- The development of a specific section on the NICNAS website on the EC Program, written in plain English, that includes regular updates on NICNAS’s EC Program activities and update reports on chemical assessments
- The examination of the current seminar/training programs associated with the EC Program with a view to better identify target audiences, objectives and appropriate outcomes. This should be done within the framework of the NICNAS Community Engagement Charter, and
- The introduction of a systematic process for the public call for nominations to the EC Program with a scheduled call occurring, as a guide, at least every two years.

Strong support was received for providing improved information on the various roles and responsibilities of each of the government agencies involved in the control and management of industrial chemicals in Australia. Such information would complement the existing guide to Chemical Assessment and/or Registration of chemicals in Australia (an initiative of NICNAS, APVMA, TGA and FSANZ) which details how the four chemical sectors are regulated at the federal level.

**Recommendation 3.2**

That NICNAS develop and publish on their website (with appropriate links) a *Who's Who (and what do they do)* Guide, covering the roles and responsibilities of the various government agencies involved in OHS, public health and environmental aspects of industrial chemicals safety assessment and management.

NICNAS currently participates in a number of major international assessment programs for existing chemicals (see [Appendix 1](#)). The benefit of internationally agreed chemical assessments lie in the ability of national regulators such as NICNAS directly use these in their national assessment programs. To date, NICNAS has set a target of at least three EC Program assessments per year to utilise overseas assessments. This has ensured NICNAS has made more chemicals safety information available on more chemicals without additional resource input. Further, NICNAS monitors international trends and regulatory activity on chemicals safety data which is held by the regulator but not generally made publicly available.

While NICNAS already provides information on national chemical safety activities, feedback has indicated that the provision of more international information on existing chemicals regulation would be of benefit and enhance awareness and understanding of current chemical issues. The information would need to be in a format and style that is relevant to Australian use and risk scenarios so as to inform stakeholder input to NICNAS.

**Recommendation 3.3**

That NICNAS develop a current awareness bulletin for publication on the website which focuses on international chemical safety information and issues relevant to the EC Program.

## CHAPTER 4: ENHANCING MECHANISMS TO IDENTIFY CHEMICALS OF CONCERN: NEW SCREENING PROCESSES

Critical to the effective management of potential risks arising from the use of chemicals is the ability to utilise existing resources and available information to identify those chemicals posing the greatest concern or risk and to decide priority setting so as to design appropriate control measures and effect immediate action. The overall prioritisation processes are addressed in Chapter 5.

While the reforms introduced into the EC Program in 1997 brought about significant improvements in identifying those chemicals to be considered for priority assessment outputs, the level of available chemical safety information remains limited when considered against the vast and diverse range of chemicals used in Australia. To this end, this review has identified that new approaches and/or tools are essential to support NICNAS's efforts in screening and evaluating information on existing industrial chemicals used in Australia as part of identifying candidate chemicals for its prioritisation process for chemicals assessment under the EC Program.

AICS contains approximately 38,000 chemicals. The majority of these have not been assessed for their effects on human health and the environment, or potential risks that may arise from exposure to them, at least in Australia. Some of these chemicals are used in high volume in Australia and some are hazardous substances that are widely used.

End-users and those potentially exposed to these chemicals, including workers, the community and industry, need information about the potential hazards and risks of industrial chemicals so that they can be used safely or substituted with safer alternatives if necessary. Increased knowledge about the hazards and effects of existing chemicals in use in Australia would benefit the community, industry and government as realistic and practical control measures could then be applied to minimise the risks to human health and the environment.

To better screen chemicals requiring assessment, three elements have been identified. These are hazard, risk surrogates (exposure and/or volume) and adverse experience (environmental and/or human health effects). These three elements are integral components to the safe use of chemicals and hence are acceptable measures for NICNAS to use, appropriately weighted, in identifying chemicals of concern.

### **Screening of AICS-listed chemicals in use**

The proposals (*Proposals 3, 4 and 5*) to screen AICS chemicals for both hazard and risk surrogate elements as a means to support the chemicals assessment prioritisation process attracted strong support from all sectors. It was noted that undertaking such a task requires a balanced and carefully managed approach by NICNAS, so as not to screen chemicals unnecessarily.

Although screening of the inventory may appear to be a daunting task, other countries have screened their national inventories and the EU is proposing a screening mechanism for existing chemicals in use in the EU. Canada has recently completed the screening of the 23,000 chemicals on its Domestic Substances List, using screening tools developed to streamline the process. This information can be made available to NICNAS under the

Canada-Australia Bilateral Arrangement, together with information on screening tools. Indeed, Canada has offered to cooperate with NICNAS with the screening of AICS.

In addition, many of the chemicals not assessed by NICNAS have been assessed under other national and international assessment schemes whereby hazard classification information and assessment reports are readily available.

### *Findings*

Identification of chemicals of concern for prioritisation for assessment under the EC Program can be set through a more targeted approach so that the unassessed chemicals of greatest hazard and risk can be screened, applying a risk-based approach and taking into account the need to develop and apply a rigorous and transparent set of screening criteria and process. NICNAS, the community, industry and government will be required to work together in the development of criteria and processes for the screening of AICS.

#### **Recommendation 4.1**

That NICNAS develop an overall framework for the screening of chemicals of concern, including the weighting of data elements (hazard, risk indicators, adverse incidents), public nomination processes and other scientific-based criteria in consultation with stakeholders and using the principles and protocol of the NICNAS Community Engagement Charter.

#### **Recommendation 4.2**

That NICNAS undertakes screening of AICS-listed chemicals for hazard and/or risk indicator elements with a focus on:

- chemicals that are on the HVICL (risk indicator element)
- unassessed chemicals on the HSIS (hazard element)
- chemicals classified as hazardous to the environment (eg. under GHS when introduced) (hazard element)
- chemicals that are carcinogens, mutagens, and/or reproductive toxicants (CMR) (hazard element)
- chemicals that are persistent, bioaccumulative and toxic (PBT) (risk indicator), and
- chemicals in use with other agreed health and/or environmental effects, eg. sensitisation and neurotoxicity (hazard element).

In undertaking this screening work, it is recommended that NICNAS build on existing overseas programs and experience as appropriate to avoid duplication of effort and unnecessary cost.

### **Surveillance, monitoring and post-market reporting for industrial chemicals**

The third element for identifying chemicals of concern and hence potential priority assessment is the reporting of adverse incidents (*Proposal 6*). In identifying how to

capture this information, a wide variety of existing reporting systems were discussed. However, these were found to be fit for specific purposes and may or may not meet NICNAS's needs. For example, certain states and territories already have systems which collect and record data on the adverse impacts of industrial chemicals. However, at the moment these data do not feed into NICNAS processes in any coordinated form. The National Pollutant Inventory (NPI) has been established as a national reporting system for point source emissions of certain chemicals into the environment but, up until recently, no equivalent system existed for human health events. The lack of any formal national nor any other coordinating system for collating and recording post-marketing surveillance, including adverse experiences and impacts arising from exposure to industrial chemicals, limits the accessibility by NICNAS to these data.

In the absence of simple and effective data collection systems, important screening information cannot inform the identification of chemicals of concern.

During the review it became clear that terms such as adverse reporting, adverse incident scheme and surveillance and monitoring are often used interchangeably but in fact meant different things to different sectors. It is therefore vital to clearly articulate what such a scheme encompasses, the role of NICNAS in coordinating such information and the use of these data.

*The need for such a system is not established nor defined in the Discussion Paper; the assessment of other alternative mechanisms, such as by using established reporting through, for example, workplace chemicals legislation, is similarly not available.....Industry therefore considers a feasibility study – to scope the nature, source and quality of surveillance and post-market data already collected – is essential, in order to fully consider the costs and benefits of this proposal.*

**Plastics and Chemicals Industries Association**

*To effectively regulate and manage industrial chemicals, it is essential that a national chemical surveillance system is implemented to collect information on the impacts of chemicals on health and the environment. This should be linked to other monitoring systems (eg cancer surveillance systems, body burden monitoring) to ensure the impacts of chemicals are properly identified.*

**National Toxics Network**

*The VTHC and our affiliates **strongly support** NICNAS taking the lead in moving to establish a nationally consistent and coordinated system of surveillance, monitoring and post-market reporting for industrial chemicals... Clearly, it will be important to ensure that any current reporting/surveillance schemes/mechanisms are 'scoped' in order to prevent unnecessary and costly duplication.*

**Victorian Trades Hall Council**

*Supported in principle, but this idea would need careful design and be subject to proper cost-benefit analysis to ensure that information was worth collecting and contributed usefully to well defined objectives.*

**Department of Environment and Conservation, Western Australia**

The strength of such a Use Experience Program is reinforced by its ability to generate community confidence that the information provided would be considered as part of the

screening process and hence part of determining the need for assessment, the selection and prioritisation for assessment and ultimately undertaking a risk assessment so as to determine appropriate risk management strategies for chemicals that may be of concern.

The issue of whether NICNAS should establish a separate Use Experience Program and/or simply provide a coordinating role in gathering such information from other bodies attracted mixed responses. Although there was strong support, particularly from the community and some government agencies, for a nationally coordinated system of post-market surveillance, monitoring and reporting (ie. a Use Experience Program) for industrial chemicals, this was generally not supported by industry. There was strong support for scoping such a system. Being able to utilise use information is vital not only to the screening process but forms pivotal exposure assessment information and hence strengthens the risk assessment process. The challenge, however, remains as to how this will be achieved.

Importantly, it is recognised that NICNAS does not have an investigative role in chemical incidents and such a role is not envisaged. The key reason for building any use experience into the NICNAS screening processes is to enhance the identification of chemicals of concern and hence better focus our priority assessment program.

### *Findings*

The utilisation of any use experience information should be taken up as one of the three elements of screening by NICNAS in identifying chemicals of concern.

### **Recommendation 4.3**

That NICNAS examine the feasibility of a nationally coordinated system of surveillance, monitoring and post market reporting.

In carrying out this work, the following guidance is provided:

- The feasibility study to be conducted in partnership with community, industry and government using the principles and protocols of the NICNAS Community Engagement Charter with open and transparent processes
- The study identify current data holdings, reporting systems, and any gaps and opportunities to further harmonise and/or streamline these activities
- Consider a 'warehousing system' that collates use experience information covering health, safety and environmental effects relevant to determining which chemicals are of national concern
- Any system be consistent with the objectives of NICNAS as defined in its legislation and include the need to protect the Australian people and the environment from the harmful effects of chemicals as well as to collect statistics in relation to chemicals
- Any system not duplicate incidence investigation/response that is already carried out by other authorities but seek to access the findings of these activities within a framework of screening for chemicals of concern
- Any system consider voluntary and/or co-regulatory mechanisms
- The type, source (eg industry government, public), purpose, protection, (confidentiality/disclosure) and use of the information be clearly articulated, and
- Use of cost effective IT solutions for information provision and storage be considered.

There is a need to better define and scope the objective, nature and source of data to be collected for a post-market surveillance system. Such a scoping study would comprise a detailed identification and analysis of data collection systems in existence nationally and internationally, together with an estimate of the potential benefits and costs. Issues such as the type of data to be collected, the source of such data, the use of collected data and the means for collecting data would require careful consideration and further consultation with all stakeholders.

### **Identifying use: engaging downstream users**

Another risk indicator that provides useful exposure information is the use to which a chemical is put. For example, a chemical that has wide dispersive use may pose direct environmental risks and/or contribute to indirect exposure of the population. While NICNAS has a clear mandate to collect import and manufacture information, it is often difficult for the introducer of a chemical to know the exact circumstances of a chemical's use once sold into the supply chain, ie. downstream (*Proposal 11*). If NICNAS can identify a downstream use, this information can assist both in screening the level of concern as well as assisting in 'fine tuning' the prioritisation of chemicals (see Chapter 5) where by a wide dispersive use or high exposure potential to vulnerable subpopulations may be factor in establishing priority assessment.

While NICNAS has some capacity to identify the downstream users via customer lists of introducers, it can only get downstream use patterns and information by relying on industry voluntary co-operation. To date this has had mixed success.

Downstream users are key stakeholders in the supply and use of industrial chemicals, however, they often fall outside the normal regulatory framework. They are often difficult to identify and NICNAS must rely on introducers for assistance to identify relevant user groups, eg. through their customer lists. As important links in the supply chain, they often have the knowledge and experience of chemicals uses, information which is of critical relevance to the screening and prioritisation process of the EC Program.

In addition downstream users are often required to implement control measures to reduce the risks to human health and the environment. Thus an early engagement in the regulatory process will alert the industry sector(s) to potential activities that may affect their businesses.

The use of a chemical is fundamental in determining its potential exposure and hence is a risk indicator. However, downstream use is not seen as a broad screening tool to be applied to some 38,000 chemicals on the AICS. Thus any request for downstream use information must be justifiable and serve a demonstrated need.

NICNAS therefore requires strategies that enable it to identify and engage downstream users only as required, on a 'chemical-specific' basis. This approach can be delivered efficiently and thus avoid the costly avenue of extending the regulation to cover formal NICNAS Registration of all end users. These data also will serve as an important tool to fine tune prioritisation for assessment.

Engaging downstream users can provide vital information to address data gaps in chemical assessment and is vital to promote safe chemicals and safe use.

### *Findings*

The identification of chemical use patterns (via early engagement with downstream users) on a needs basis only would provide a mechanism to differentiate the risk potentially posed by a chemical and hence the need for its assessment.

#### **Recommendation 4.4**

That NICNAS develop a framework to identify the circumstances under which downstream use information is sought as being necessary for prioritisation. A key element of the framework is that downstream use needs to be:

- specific
- transparent
- meet a demonstrated need, and
- explore voluntary and/or co-regulatory pathways.

Note: It is noted that downstream use information is also part of information that may be required for the risk assessment process itself, and the above principles should also be taken into account (see *Recommendation 6.2*).

## CHAPTER 5: IMPROVING EFFICIENCY (PARTS A AND B)

Consistent with the aims of enhancing the efficiency and effectiveness of the EC Program, a number of administrative and process improvement options were identified and proposed in the Discussion Paper. Two central themes were considered under this group of proposals. One addressed the need for a more transparent approach to selecting, prioritising and addressing chemicals issues. The other raised the need for more effective cooperation between NICNAS and its partners so as to enhance the implementation of chemical risk assessment outcomes.

### **Part A – Redesigning internal processes** *(Proposals 7, 8, 9 and 12)*

A range of options was considered to enhance the transparency of NICNAS's decision-making processes, particularly the response to concerns by stakeholders and the screening and selection of chemicals for assessment (*Proposals 7, 8 and 9*). The proposals were overwhelmingly supported by all sectors and are expected to increase the efficiency and effectiveness of NICNAS internal administrative processes.

#### **Filtering and selection of chemicals**

Under current processes, inquiries and concerns raised by stakeholders on chemicals in use are fed into the selection and prioritisation of chemicals for assessment through an internal assessment process. While this process is conducted against formally set criteria, the decisions and conclusions are not always transparent or clearly stated. Further, these criteria are not published and have not been updated since 2000.

The development of transparent procedures to appropriately filter out and redirect non-NICNAS matters was strongly supported and is expected to result in enhanced community awareness and increased confidence in the scheme.

Similarly the development of a more open process for choosing and screening of chemicals for possible assessment, in consultation with stakeholders, was strongly supported.

The development and publication of scientifically based criteria for the selection and prioritisation of chemicals, including the publication of screening decisions, will add to the transparency of the decision-making processes within NICNAS. In addition, the development of new criteria would provide an opportunity to incorporate international best practice, taking account of current concerns such as persistent, bio-accumulative and toxic (PBT) chemicals and carcinogenic, mutagenic and reproductive toxicants (CMR).

#### **Findings**

NICNAS needs to enhance the transparency of its decision-making processes for the, filtering and prioritisation of chemicals under the EC Program.

**Recommendation 5.1**

That NICNAS develop, modify and publish processes to filter out and redirect non-NICNAS matters and determine the level of response and/or assessment required.

**Recommendation 5.2**

That NICNAS establish a working party to develop scientifically-based criteria for the prioritisation of chemicals for assessment, including priority existing chemicals.

**Recommendation 5.3**

That NICNAS publish the prioritisation process and decisions on the NICNAS website.

**Simplified secondary notification**

In general, the secondary notification of existing chemicals originally assessed as new chemicals is restricted to a small number of introducers, often only one. The current process is lengthy and no flexibility is available under the IC(NA) Act.

The proposal to streamline the secondary notification process (re-assessment) for existing chemicals originally assessed as new chemicals (*Proposal 12*) was overwhelmingly supported at both the public forums and in written submissions, with a more flexible approach, using the new model, the favoured option.

A more efficient process is to use the New Model (see [Appendix 5](#) for details) for the program, where the level of response can be determined during the screening process, and the appropriate level of assessment determined. Greater flexibility is consistent with the aim to enhance the efficiency and effectiveness of the EC Program.

Use of the New Model for the program, with its increased range of assessment types, will result in some cases in markedly reduced timeframes without compromising the integrity of the assessment process.

**Findings**

Modify the secondary notification provisions of the IC(NA) Act to allow the recommended increased range of assessment types to be available for the reassessment of existing chemicals previously assessed as new chemicals.

**Recommendation 5.4**

That NICNAS streamline the secondary notification process for existing chemicals originally assessed as new chemicals:

- using the new chemicals assessment process with its shorter timeframes, or
- using the range of assessment types as developed as options for greater flexibility.

## **Part B – Broadening the bond with governments** *(Proposals 13, 14, 16 and 20)*

The complexity of the Australian regulatory system means that many of the desired outcomes from NICNAS assessments depend on effective cooperation with other regulatory authorities, particularly at the state and territory level.

NICNAS has a formal MOU with the states and territories, however, this review has identified that the current arrangement is insufficient to support a strong assessment program capable of delivering the desired outcomes.

Similarly interactions between the various state and territory agencies and with their federal counterparts have been reported as deficient, as is the interaction between NICNAS and some other federal agencies. A cooperative and coordinated approach between the various levels of government is often required for the effective delivery of desired outcomes of improved risk management.

### **Relationship between NICNAS & state & territory government agencies**

The proposal to broaden NICNAS MOU arrangement with states and territories to improve the relationship with agencies not directly represented on the MOU committee (*Proposal 13*) was overwhelmingly supported by all sectors, both at public forums and in written submissions.

A need was identified, particularly by the community sector, to clarify the roles of NICNAS and the state and territory agencies. The need to protect commercial business information in any arrangement was noted by industry.

### **Relationship between NICNAS and other federal government agencies**

The proposal to clarify the roles of the various federal agencies and existing networks, and establish the appropriate forums to ensure proper regulation of industrial chemicals at the national level (*Proposal 14*) was overwhelmingly supported by all sectors, both at public forums and in written submissions. Comment suggested that a consistent regulatory approach would ensure better regulatory efficiency and higher quality outcomes.

In general, all sectors strongly support options proposed to enhance NICNAS's relationships with other regulatory agencies, thereby improving the scheme's effectiveness.

### *Findings*

Better define the roles and responsibilities of the various regulatory authorities, at all levels, and enhance the cooperation between NICNAS and the state and territory health and environment agencies by broadening the NICNAS MOU group.

### **Recommendation 5.5**

That NICNAS explore with states and territories improved processes for coordination and cooperation including under its MOU group.

### **Recommendation 5.6**

That NICNAS continue to participate in chemicals management forums to ensure harmonised and streamlined regulation of industrial chemicals at the national level.

## Bilateral arrangements with other countries

NICNAS has an effective Bilateral Arrangement with Canada for the notification and assessment of new industrial chemicals and is pursuing a similar arrangement with the USA.

NICNAS participates in the international existing chemicals assessment programs, however, it has no formal bilateral arrangement with other countries.

The proposal to pursue a similar arrangement for the EC Program as currently exists for the new chemicals program with Canada was strongly supported. Further, the proposal to develop bilateral arrangements for existing chemicals with other major trading countries (*Proposal 16*) was also strongly supported by all sectors, provided that assessment standards were maintained.

One submission noted that assessments conducted should be risk-based, and another noted that commercial business information needed to be protected.

### Findings

Bilateral arrangements provide effective means for the exchange of assessment reports and information on chemicals hazards and risks. Further, they contribute to maintaining best practice in assessment methodology.

#### Recommendation 5.7

That NICNAS explore the extension of the Bilateral Arrangement with Canada to include existing chemicals.

#### Recommendation 5.8

That NICNAS explore the development of similar arrangements with other major trading countries.

## Improved uptake of recommendations

The proposal to improve the uptake of recommendations arising from PEC assessments (*Proposal 20*) was generally welcomed by all sectors, both at the public forums and in written submissions. While it attracted strong support from the broader community, it drew cautious support from the other sectors including industry and some government agencies.

*The MCA supports the proposed changes, and believes that the implementation of all three approaches would improve both stakeholder acceptance of NICNAS's recommendations and compliance with resulting licences.*

**Mineral Council of Australia**

*Supported, noting that greater input from implementing regulatory agencies is required to ensure that NICNAS recommendations are reasonable, practical, and consistent with the risk-based controls imposed through other regulatory approaches.*

**Department of Environment and Conservation, Western Australia**

*... irrespective of any changes resulting from Proposals 18 & 19, NICNAS must continue to facilitate uptake of recommendations by implementing suggestions as outlined in this proposal.*

**Victorian Trades Hall Council**

*There is important need to confirm the role of the states and territories in regularly measuring the uptake of NICNAS recommendations. This does not appear to be a NICNAS function.*

**ACCORD Australasia**

*There was strong support for a greater role for states and territories to ensure the uptake of assessment recommendations and feed information back to NICNAS. A nationally coordinated approach was needed to frame assessment advice.*

**NICNAS Community Engagement Forum**

*The proposed broadening of the NICNAS MOU arrangements with the States and Territories (as per Proposal 13) will facilitate the enhanced consultation that is suggested here. Through consulting with MOU groups on assessment outcomes and draft recommendations at an early stage in their development, NICNAS will greatly increase the likelihood that its recommendations are ones that can be implemented and enforced.*

**Department of Environment and Conservation, NSW**

Further, the comments received on the suggested approaches to achieve improved uptake of recommendations were mixed. From these comments, it is possible to identify three important issues as impacting the uptake of recommendations, and for which a number of tailored solutions are needed.

The first concerns the framing of recommendations arising from NICNAS's PEC assessments, which impacts their effective implementation by affected parties. To this end, proposals to improve the wording of recommendations combined with early consultation with the relevant stakeholder are supported as important and effective means to facilitate the uptake of recommendations.

### **Findings**

NICNAS needs to better frame and target its recommendations by tailoring them to address the identified problem, enhancing the focus and appropriateness of recommended actions.

### **Recommendation 5.9**

That NICNAS increase and broaden its consultation with stakeholders during the assessment process and before recommendations are finalised to ensure that recommendations can be implemented.

However, in isolation, improved phrasing of recommendations was considered to be a minor part of the solution required to address what may be a more complex issue. This is because implementation of recommendations is also affected by the processes applied by

the implementing bodies, such as national frameworks for controls, eg. government agencies responsible for OHS.

This brings to the fore the second concern raised in comments on *Proposal 20*, namely the complex nature of the chemicals management framework and the multitude of government players, both Commonwealth and state and territory, involved in chemicals regulation. This complexity has the potential to act as a barrier impacting not only the timely implementation of NICNAS's recommendations but also the coordination of work programs and alignment of priorities across various agencies. This in turn has the potential to further impact the safer use of chemicals by industry and consumers alike.

### *Findings*

NICNAS needs to enhance cooperation with stakeholders to support the uptake of recommendations through improved consultative measures to be implemented throughout the assessment process starting with its initiation and through to conclusion. It is noted that the broadening of the NICNAS MOU group would contribute significantly to improved consultation processes.

### **Recommendation 5.10**

That NICNAS use action statements that are evidence-based, specific to the needs identified, achievable, and practical and be directed to the most appropriate body for implementation.

A third issue that was highlighted in the comments was the role of NICNAS in monitoring the uptake of recommendations.

It is noted that a key measure of effectiveness of the EC Program is the level of uptake of report recommendations, as these aim to ensure the safe use of chemicals and thus protect human health and the environment. As such, ongoing monitoring and reporting on implementation of outcomes is essential to achieving the objectives of the EC Program. Reporting can be achieved through a range of means including, direct engagement by NICNAS through co-regulatory and/or voluntary industry activities, and indirectly via other Commonwealth agencies or state and territory bodies.

NICNAS acknowledges that state and territory agencies effect NICNAS's recommendations through state based legislative instruments within the existing national frameworks for OHS and public health. Feedback on the usefulness of and the uptake of NICNAS's recommendations by the states and territories is currently achieved through the MOU group. The enhancement of state and territory cooperation mechanisms will provide additional means for the enhanced uptake and monitoring of NICNAS's recommendations.

Past evaluation by NICNAS of the uptake of EC Program assessment recommendations by peak bodies (including ASCC) revealed significant time delays in the consideration and implementation of recommendations. While this has improved, delays continue to occur which may reflect the competing organisational priorities and the need for greater level of coordination between NICNAS and peak bodies. Such delays translate into a lack of formal advice on the adequate controls necessary, and thus create confusion within the industry and lead to poor compliance and ultimately raise concerns as to the level of protection afforded to human health and the environment.

It is important to recognise that implementation of recommendations by industry is subject to a combination of co-regulatory and voluntary arrangements. To date, NICNAS has not been able to establish an effective engagement process, in cooperation with industry, to monitor and report directly on the uptake of its recommendations or the effectiveness of co-regulatory and voluntary approaches. This has hindered its efforts to identify and implement measures in support of streamlining compliance by industry.

### *Findings*

While improved phrasing of the recommendations and enhanced consultative measures will support and facilitate the uptake of recommendations by stakeholders, including governments, industry and users of chemicals, it is noted that a more rigorous investigation of the complex and multi-layered regulatory arrangements is needed to identify the underlying barriers to achieve a streamlined and harmonised uptake of recommendations by all concerned parties. Integral to this is the need to consider the effectiveness of co-regulatory and voluntary industry compliance programs. Given that this concerns matters of broader chemicals regulation and policy parameters, any consideration of this issue is beyond the scope of this review.

### **Recommendation 5.11**

Consistent with Recommendation 1 of this report, that NICNAS refer the proposal to investigate the barriers to effective implementation of NICNAS's recommendations in a streamlined and harmonised manner and the effectiveness of co-regulatory and voluntary industry compliance programs to the Ministerial Taskforce on Chemicals and Plastics for their consideration.

## CHAPTER 6: BROADENING ASSESSMENT OPTIONS

The current priority existing chemicals (PEC) assessment program is not flexible enough to adequately respond to the variety of chemical concerns of stakeholders and new types of targeted assessment are proposed (*Proposal 17*). Adequate assessments of existing chemicals depend on obtaining sufficient information from stakeholders. Thus, consequential to the proposed changes in assessment types, concomitant amendments to data gathering powers linked to assessment types will be needed (*Proposal 10*).

### Background

The NICNAS EC Program currently has a number of ‘products’ or types of assessment which it uses to respond to the concerns of stakeholders; these are detailed in [Appendix 1](#). Only one assessment product type is supported by legislation (full and preliminary PECs). Other assessment outputs are referred to generically as ‘other’ and include NICNAS Alerts and Information Sheets. The regulatory status of such documents required clarification.

Further, due to the complexity of the PEC (legislative procedures and processes) NICNAS lacks the flexibility to respond quickly and/or in more resource efficient manner. This can stifle both efficiency and innovation in the risk assessment process, reduce the capacity of NICNAS to be responsive to community concerns and is unnecessarily costly as the principles of minimum effective regulation are not achieved.

With about 60 existing chemicals already on the candidate list awaiting assignment as PEC assessments, the potential for NICNAS to respond in a more flexible and cost efficient manner to chemicals of concern in Australia remains limited within the current program arrangements.

There is considerable pressure from the community to have more safety information on more existing chemicals. The challenge is to find more efficient and flexible ways of assessing chemicals.

It is noted that the screening and prioritisation of chemicals as proposed in Chapter 4 will, in itself, generate basic safety information which will be adequate to assure the ongoing safety profile and use of a large number of existing chemicals. For those chemicals that are identified as requiring some sort of priority assessment, the challenge is to ensure the risk assessment is ‘fit for purpose’ rather than apply a single PEC process.

It is crucial that NICNAS is able to access use information, exposure and/or safety data necessary to conduct adequate assessments. In the past NICNAS has experienced difficulties in obtaining the necessary information from stakeholders.

With the recommendation for NICNAS to introduce a greater range of assessment products and related processes, NICNAS will also be able to obtain the information appropriate to each assessment type.

### Findings

There was strong support at both public forums and in written submissions for a greater range of assessment types and a more flexible assessment system that shaped the assessment outputs according to the regulatory issue.

Industry cautioned that any increase in flexibility should not result in greater regulatory complexity. As this work will need to be further developed, there were useful suggestions as to the considerations that needed to be given in articulating the regulatory/legislative status, administrative processes, obligations and requirements.

Benefits of the expansion of the types of assessments for the EC Program include:

- faster response when required, eg. response to an emerging concern
- more appropriate response to the level of concern
- identification of need for further action
- more information and guidance for stakeholders about a greater number of chemicals, including more information available for the community, and
- more flexibility in response.

The assessment of more chemicals is expected to benefit the community as more information about more chemicals in use will be publicly available. Similarly more information about more chemicals will benefit industry as more information about possible alternatives to high risk chemicals will be available.

Greater flexibility in the number of assessment and related process options available to NICNAS is expected to lead to enhanced efficiency and better utilisation of resources at NICNAS. The appropriate type of assessment could be chosen to address the concern without compromising health, safety or the environment.

#### **Recommendation 6.1**

That NICNAS develop new types of assessment product based on intended output and purpose.

The following framework is provided to guide this work:

- A. Consultation processes should follow the principles and protocols of the NICNAS Community Engagement Charter, with open and transparent processes
- B. Each assessment type needs to be fit for purpose and the level of resource input commensurate with the risks posed and the need for, and type of, regulatory underpinning
- C. The regulatory status of each assessment type should be clearly articulated including in relation to data gathering powers, legislative underpinning, comment periods and appealable matters, and any other regulatory 'relationship' with the relevant national regulatory control framework. For example, it may be that information products providing advice would need legislative support only for the collection of information
- D. The administrative processes for the various assessment types should be clearly articulated and designed to enhanced flexibility and efficiency (eg duration of assessment and its comment phases, extended comment phase for the more comprehensive assessments, the need for Ministerial or Director initiated declaration for assessment, chemicals to be assessed under the 'limited' or targeted approach or where a rapid response is required.
- E. Assessment types should include (but not necessarily be limited to):

**Recommendation 6.1** *(continued)**(1) Assessment aimed at providing health, safety and environmental safety and other related information*

An information product to be used where NICNAS needs to provide factual information about chemical safety matters or emerging issues that will assist stakeholders in continuing to use chemical safety, or address a lack of credible information in the public domain. Examples include:

- the results of screening decisions, particularly where a decision of 'no further action' is taken
- a summary of information obtained by NICNAS for a chemical, eg. summary of an OECD SIDS report, and
- a summary of information about an emerging issue, eg. nanomaterials.

*(2) Information/Assessment product aimed at providing technical advice or guidance*

A product to be used when advice or guidance is to be included with the information, eg. advice for safe use, handling and disposal of the chemical. These may require legislative underpinning to gather information from stakeholders. Examples include:

- a response to a local concern, where advice to users of the chemical is necessary
- an update on an emerging concern where action locally is advised
- a response to a referral from another government agency/department, where information and advice about a particular chemical is given, and
- a screening assessment.

*(3) Assessment aimed at providing a range of regulatory recommendations.*

The current full PEC Assessment process would remain as a supported activity. In addition NICNAS may consider developing a framework for preparing a range of assessment output such as:

- short hazard assessment about a particular endpoint
- a targeted exposure assessment or
- the full PEC assessment.

Assessment reports would normally contain recommendations, ie. proposals for regulatory action by government, and advice, eg. for safe handling. Assessments could be of a 'limited' or targeted nature, focussing on particular aspects of the chemical, eg. hazard classification, where a full risk assessment was not warranted. An assessment report may be the appropriate response for any of the concerns raised by stakeholders.

The broadening of NICNAS's powers to gather information for assessments other than priority existing chemicals (PECs) was strongly supported by the community sector and endorsed in principle by government agencies. However, industry was generally reluctant to support the proposal without further clarification. A blanket expansion of information gathering powers was not supported by industry.

The importance of NICNAS being able to obtain the information it needs for adequate risk assessment was noted in several written submissions. In a written submission from the community, it was recommended that the assessment of a chemical should consider its full life cycle so information from all potential end-users was necessary. Support for the provision of a number of specific information requirements for assessment was raised at public forums, including information on breakdown products, clinical data, and information on other chemicals present, eg. for consideration of synergistic effects.

Given that information/data gathering powers in the IC(NA) Act are integrally linked to the assessment process, and noting the support for development of new assessment types, it would follow that any change in the assessment type would need a consequential consideration of the information gathering powers needed for each assessment type.

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**Recommendation 6.2**

Consequential to Recommendation 6.1, that NICNAS should develop the information requirements for each new assessment type including any legislative amendment to current data gathering provisions associated with the EC Program.

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## CHAPTER 7: INCREASING THE LEGISLATIVE REACH: ENHANCED CONTROL POWERS

The Review of the NICNAS EC Program is an internal review focussed on identifying options and opportunities for delivering innovation, streamlining and improved regulatory efficiency, and reducing compliance burden while enhancing the safer use of industrial chemicals. Such options would be expected to be achievable within the current legislative mandate of NICNAS. However, given that the Review has achieved broad engagement and has encouraged open processes in identifying issues, it is not surprising that issues were raised that extend beyond the current mandate of NICNAS in relation to suggestions for NICNAS to be able to ban, severely restrict, or control certain chemicals (*Proposals 18 and 19*).

### Background

It is noted that the COAG has announced, as part a new wave of reform commitment in response to the Banks Report, the establishment of a Ministerial Taskforce on Chemicals and Plastics to address with priority a number of issues in the sector including a national chemicals policy framework. The COAG decision in February 2006 reflects the fact that the regulation of the chemicals and plastic is complex, involving 144 pieces of legislation of which the IC(NA) Act is but one. This myriad of legislative instruments covers Commonwealth, state and territory and local governments.

As part of this review a number of factors have been highlighted that contribute to regulatory complexity and hence barriers for both industry compliance as well as the rapid translation of the NICNAS assessment that identify the risks, and the mechanism for controlling that risk, into actual safer chemical use for workers and consumers.

With respect to chemicals regulated via NICNAS, there are frameworks for ensuring national consistency of regulations within the OHS sector (through National Model Regulations for the Control of Hazardous Substances in the Workplace), via the OASCC and public health sector (through the Standard for the Uniform Scheduling of Drugs and Poisons – SUSDP) and via the National Drugs and Poisons Scheduling Committee – NDPSC. Currently, an Environment Risk Management Framework for Chemicals (NChEM) is being developed under the auspices of the Environment Protection and Heritage Council. This will provide for a level of national consistency through cooperative arrangement by the jurisdictions.

While existing national consistency frameworks are designed to reduce duplication and avoid unnecessary divergence in regulatory approaches across the various jurisdictions, industry have highlighted in recent reviews and reports, their concern over the complexity of existing arrangement and thus the potential for duplication and inconsistency between these regulatory regimes. Industry concerns focus on the fact that state and territory government often have separate arrangements for regulation, administration, policy development and enforcement. The proposals for improving the regulatory uptake of NICNAS recommendations, (*see Chapter 5*) demonstrates aspects of this complexity.

The proposals that NICNAS increase its legislative powers to ban or restrict certain chemicals (*Proposal 18*) and that NICNAS increase its powers to control the use of (designated high risk/high hazard) industrial chemical (*Proposal 19*) have proved, not

surprisingly, to be the most controversial. There has been a wide diversity of views in relation to these issues.

Community groups strongly support the concept that NICNAS have powers that enable it to ban, phase-out, restrict the use or, by other mechanisms, control the use of certain high hazard and high-risk chemicals, noting that current powers of NICNAS are less than those of 'similar regulatory bodies'.

It is noted that comment supporting the proposal also stressed the need to ensure any action to ban or severely restrict chemicals by NICNAS be undertaken in cooperation with the jurisdiction so as to avoid duplication of regulation.

Comment from government agencies was mixed, with either strong support, provided that consultation was undertaken with the relevant agencies, or no or little support.

There is concern that state and territory powers would be duplicated without consultation with them and that the proposed enhanced powers of control would be broad and extend to all industrial chemicals.

Comment from industry was generally not supportive of the proposals, on the basis of possible duplication of regulation with the states and territories, and that further consultation with the relevant stakeholders is necessary before any consideration of enhanced powers for NICNAS.

*It has been disappointing to see that at times recommendations resulting from PEC assessments are not picked up, or not picked up in a timely manner, by the relevant state agencies.*

**Victorian Trades Hall Council**

*DEC strongly supports NICNAS strengthening its .....NICNAS needs to be able to set the appropriate controls, restrictions or conditions, in consultation with State and Territory regulators.*

**Department of Environment and Conservation, NSW**

*CME supports this proposal, with qualifications. To the extent that the proposal results in streamlining current regulatory function across jurisdiction, this would achieve greater consistency and simplicity and would be benefit to industry. However, we would not support the proposal if it results in a duplication, rather than replacement of other jurisdiction powers. We recommend that the proposal only proceed in the context of agreement with other regulatory agencies to create a single stream of regulation in this area.*

**Chamber of Mineral and Energy, Western Australia**

*The Recommendation requires detailed analysis of the many issues associated with amending the scope of NICNAS's powers, in line with the objectives and aims of the Banks Report in line with the COAG Principles.*

**Plastics and Chemicals Industries Association**

*The Health Consumers' Council supports the enhancement of NICNAS's legislative powers.....*

**Health Consumers Council, Western Australia**

*DEWR does not support the proposals..... There are existing mechanisms within the regulatory framework which can already achieve legislative bans or restrictions on the use of certain industrial chemicals. DEWR would see the role of NICNAS in this area as the provider of evidenced based recommendations in support of any such legislative action to ban, phase-out or restriction, along with an economic assessment.*

**Australian Government Department of Employment and Workplace Relations**

On the other hand, the proposals for enhanced powers received more support at the public forums, including support from attending government and industry. This may reflect a more interactive discussion of the proposals than was possible in the Discussion Paper.

Certainly, there was support for a more nationally consistent approach to the regulation of industrial chemicals. However, it is noted that such considerations are not for this Review and will be addressed in the COAG's reform processes instead.

The EPHC Chemicals Working Group has indicated support for strengthening the capacity of NICNAS to determine controls (including bans and restriction) as a mechanism of streamlining environmental controls nationally. Many chemical management issues are common to states and territories, and nationally coordinated decisions on action and approaches are considered by the EPHC Chemicals Working Group to be the simplest, most effective and efficient way to deal with such issues. This has the benefit of achieving consistent approaches across all states and territories to manage and, where necessary regulate chemicals that link directly to NICNAS decisions in order to better implement environmental recommendations.

Under the proposed reforms in the environmental regulation, NICNAS would then be able to select a management tool or requirement (developed by jurisdictional environmental agencies) that is appropriate to prevent or mitigate the risks associated with an individual chemical, from regulatory to voluntary. NICNAS would be able to set the appropriate controls, restrictions or conditions, in consultation with state and territory authorities. The states and territories would then manage the implementation of controls under their own control of use and other legislation.

It is noted that such a partnership approach between NICNAS can only operate by formal agreement with the state and territory environmental protection authorities.

The support by the EPHC Working Group for NICNAS to have certain powers granted by the states and territories under the proposed NChEM, reflects the fact that currently there is no national consistency model framework for environmental management of chemicals. Thus the NChEM proposal of linking NICNAS decisions on controls to implementation by states and territories provides a streamlined approach to achieving national consistency. Experience gained from NICNAS working with the EPHC's proposed NChEM system once available could further inform the COAG Ministerial Taskforce on Chemicals and Plastics in its consideration of wider national reforms for the regulation of chemicals and plastics

### **Recommendation 7**

Consistent with Recommendation 1 of this Report, that NICNAS refer the range of issues raised in relation to the suggestion for NICNAS to be able to ban, severely restrict, and/or control certain chemicals, to the COAG Ministerial Taskforce on Chemicals and Plastics.

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# APPENDIX 1: ANALYSIS OF INTERNATIONAL EXISTING CHEMICALS PROGRAMS – CONDUCTED JANUARY 2003

## Background

Existing chemicals amount to the vast majority of chemicals on the market worldwide. For example, in the European Union (EU) it is estimated that existing chemicals account for more than 99 % of the total volume. However, unlike new chemicals, existing chemicals have not been subject to the same testing requirements and assessment before being placed on the market. Consequently, there is a general lack of knowledge about the properties and uses of existing substances that represent the vast number of chemicals on the market.

In national schemes, ie. Canada, NZ, USA, EU and Australia, existing chemicals are generally defined as chemicals that were in use between a designated time-period when the schemes were being established. Each scheme has an inventory of existing chemicals, though in some schemes substances can be added to this list, ie. it is not a closed list, such as Canada, USA and Australia.

Up until recently, overseas programs have generally assessed existing industrial chemicals on a priority basis, eg. EU, Canada and USA. This has allowed regulatory programs to focus their resources on those chemicals considered to present the greatest risk to human health and/or the environment. Each overseas regulatory authority has developed its own prioritisation framework to identify such chemicals. However, existing chemicals policy is presently, or has recently been, under review in several countries, ie. Canada, New Zealand, EU. An analysis of overseas existing chemicals programs has been undertaken to identify how overseas regulatory authorities approach the assessment of existing chemicals, what are the changes taking place and are there common trends emerging.

## Overseas existing chemical programs

NICNAS undertook a literature search to evaluate overseas programs that assess existing chemicals. The amount of readily available information about each program varied and, thus, overviews were only prepared on existing chemicals programs in:

- Canada
- European Union (EU)
- United States of America (US) and
- New Zealand (NZ).

For the EU, an overview is provided of both the present and proposed existing chemicals program, called the Registration, Evaluation and Authorisation of CHemicals (REACH). The current EU program undertakes risk assessments on a priority basis. Under the proposed REACH system, companies will be required to register all chemicals manufactured and imported into the EU at > 1 tonne per annum, and provide a base set of data. It is anticipated under REACH that the rate of assessments will accelerate; it is estimated that 30,000 existing chemicals are marketed in volumes above 1 tonne in the EU, yet over approximately 6 years (nearly) finalised assessments have been carried out on only 41 priority substances under existing regulations.

There is no single chemical assessment scheme in the USA. Instead there are several different organisations that evaluate existing chemicals. Consequently, the overview focused on the activities of the US Environmental Protection Agency (US EPA), which oversees chemical assessment schemes such as the Integrated Risk Information System (IRIS), and the Agency for Toxic Substances and Disease Registry (ATSDR) run by the US Department of Health and Human Services. Recently, the US EPA introduced the High Production Volume (HPV) Challenge program, in response to the lack of data on high volume chemicals.

The Canadian scheme is also a risk assessment program focusing on priority chemicals which under amended legislation will systematically categorise approximately 23,000 substances by September 2006, and if necessary, screen existing chemicals. The aim is to speed up the assessment and selection of priority substances for review.

The NZ scheme, which became effective for industrial chemicals in 2001, aims to complete hazard classifications on all existing substances by 2006. It is estimated that a total of 70,000 substances (single, mixtures and groups) will be classified. No assessments of existing substances will be conducted before the hazard classification work is completed.

Detailed overviews of all the above existing chemical programs are included as attachments, below.

## **Summary of trends/issues between overseas existing chemical programs**

The aim of this overview is not to comment on the potential benefits or failings of the overseas schemes examined. Instead, a summary of trends and issues identified for these overseas existing chemicals programs are highlighted below to encourage discussion on the different approaches overseas existing chemicals programs have taken or propose to take.

### ***Hazard or risk based scheme?***

Existing chemical schemes are generally risk based, and although NZ recently adopted a hazard-based scheme, risk assessments can still be conducted on a priority basis.

### ***Single entity or product based scheme?***

Existing chemical schemes generally assess a single chemical entity, however, the NZ scheme also assesses products.

Within the single entity based programs there has been a trend for some schemes to categorise structurally similar chemicals and assess them as a group. This approach has been taken in the US HPV and existing EU schemes for chemicals such as linear alkyl benzenes, eg. the EU assessed as a single group these chemicals with an alkyl chain group of C<sub>10</sub> – C<sub>13</sub> carbon atoms.

### ***Are all existing chemicals assessed, or 'priority' chemicals only?***

Overseas existing chemical schemes have generally assessed a small number of 'priority' existing chemicals, that is, chemicals considered to present the greatest risk concern to human health and/or the environment.

Recently, the Canadian, NZ and proposed EU REACH schemes require a level of assessment for all existing chemicals:

- *Canada*: all existing chemicals are being categorised and priority chemicals undertake a screening assessment to determine whether they should go on the Priority Substances List (PSL). Substances on the PSL are given priority for analysis of potential risks to human health and the environment.
- *NZ*: hazards of all existing substances (single chemicals and mixtures) are determined, and substances classified and assigned controls where appropriate.
- *EU REACH*: phased in registration of basic information on all existing chemicals exceeding a production volume of 1 tonne (including preliminary risk assessment) by manufacturers and importers. For the large majority of chemicals (estimated at more than 80%), there would be no need for further assessment.

### ***What types of chemicals are considered a 'priority' and how are they identified?***

Although each overseas scheme has an approach for identifying priority chemicals that generally takes account of both human health and environmental concerns, there is no consistency in how the criteria are applied. For example:

- *Canada*: categorise chemicals based on potential exposure to the general population and persistent, bioaccumulative and toxic (PBT) criteria. If the criteria are met, a screening assessment is conducted. Based on outcomes of screening assessments a full risk assessment may be done.
- *NZ*: although a hazard based scheme, a priority list of nominated potential reassessments is maintained. Reassessments are where the risks and benefits of a substance are reconsidered. Reassessments have to be justified and may be paid for by sponsors or the NZ regulatory authority.
- *Current EU scheme*: only assesses high production volume chemicals, ie. are produced or imported into the Community in volumes above 10 tonnes per year, using an exposure effect model to score for human health and environmental concerns and, thus, prioritise them.
- *EU REACH*: the proposed scheme is a tiered phase-in of information in the next 3 to 11 years based on volume, with a priority on obtaining information (within 3 years) for those chemicals that are category 1 and 2 carcinogens, mutagens or reproductive toxicants (CMRs).
- *US*: different programs with different prioritisation criteria eg. EPA manages a chemical program that prioritises chemicals that are PBTs. In contrast, ATSDR ranks existing chemicals based on scores for

frequency of occurrence at National Priorities List sites, ie. sites where there are releases or threatened releases of hazardous substances, toxicity and potential for human exposure.

#### **Who is responsible for generating and assessing the data?**

It is generally the responsibility of industry to generate and provide data to the regulatory authorities for assessment. Only the US EPA and the present and proposed EU schemes require that all companies who have submitted data regularly update the information:

- *US*: under the Toxic Substances Control Act 1976, information on production volume is required every 4 years.
- *Current EU scheme*: information on new uses that change the type, form, magnitude or duration of exposure of man or the environment to the chemical and new data on physicochemical properties, toxicological or ecotoxicological effects is required every 3 years.
- *EU REACH*: change in identity of manufacturer or importer, significant changes in volume, new uses, significant new risks and changes in proposed classification have to be notified.

Presently, all regulatory authorities assess the data. However, the proposed EU REACH scheme will shift the responsibility to industry for generating and assessing the data and risks of using the substance.

#### **Do schemes obtain use and exposure information?**

With the exception of the NZ scheme, national schemes routinely obtain use and exposure information on existing chemicals. However, the source, and hence 'quality', of the exposure data varies between the schemes. Some schemes obtain 'direct' data while others do not.

- *Canada*: a number of data sources are utilised at the categorisation stage to determine human and environmental exposure, including release/emissions from the National Pollutant Release Inventory; survey in the provinces; quantity and use codes from DSL; modelling data; and international reports.
- *Current EU scheme*: manufacturers and importers supply exposure data.
- *EU REACH*: estimate of human and environmental exposure is required at the registration stage.
- *US*: EPA often uses volume as a surrogate for exposure, which is collected every 4 years. ATSDR determines the potential for human exposure based on the concentration of the substance in environment media and the exposure status of the populations.

Presently, information on use and exposure arising from downstream users (including formulators) is not readily available in national programs. However, the EU REACH scheme proposes to extend responsibility along the supply chain, with downstream users providing information on use and exposure.

It is also worthwhile noting that within the EU at present, each Nordic country (Norway, Sweden, Denmark and Finland) has its own Product Register; national legislation requires manufacturers and importers to declare chemical substances and products to a Product Register. Furthermore, much of the information provided to the Product Registers is used as support for national and EU risk assessments.

#### **Are modelling data used?**

Generally, modelling data has only been used routinely for environmental endpoints, as actual data is usually not available. However, some national authorities use modelled data to predict adverse effect to human health. For example:

- *Canada*: uses quantitative structure-activity relationships (QSAR) in their current program of categorising chemicals.
- *US*: models may be used in certain circumstances in the integrated risk information system (IRIS) managed by the EPA.
- *EU*: proposed REACH scheme makes the development of modelling and screening methods for assessing the potential adverse effects of chemicals on the endocrine system a research priority, along with the development of in vitro test methods in general.

### ***Do national schemes focus on issues identified of concern?***

With the exception of NZ, overseas schemes focus on chemicals identified of concern; the Canadian, US EPA and proposed EU REACH scheme all give priority to persistent, bioaccumulative and toxic (PBTs) chemicals.

Although there is no single scheme for the assessment of existing chemicals in the US, there are chemicals programs that focus on issues of concern. For example, US EPA recently announced it is to manage a program that will examine the potential health risks associated with certain chemical exposures, ie. Voluntary Children's Chemical Evaluation Program.

### ***Do schemes allow chemicals or specific uses of chemicals to be banned?***

Generally, the assessment schemes can only implement measures to control the use of an existing chemical, ie. are approval schemes, although stringent measures may result in the discontinuous use of an existing chemical for a specific use. However, this is not the case for the NZ, US and proposed EU scheme:

- *NZ*: can withdraw approval following a reassessment, thus making its use, manufacture and importation illegal
- *US*: EPA can limit or prohibit use
- *EU*: proposed REACH scheme can introduce restrictions (including banning)

### ***Is there public comment on the review programs or access to information?***

All these assessment schemes allow public comment on draft reports with the exception of the present EU program, although public interest groups can provide input. Additionally, all the overseas schemes make available to the public published reports, facts sheets and/or lists of approved substances.

However, the proposed EU REACH scheme makes increased transparency a key objective, and acknowledges consumers 'right to know'. That is, the community has a right to access information about the chemicals to which its members are exposed, enabling them to make informed choices and avoid products containing harmful chemicals. The scheme proposes that the public should have access via the Internet to the non-confidential information on chemicals assessed under REACH.

### ***Are national assessments used by other overseas programs?***

With the exception of NZ, national schemes routinely feed their assessments into international programs. For example:

- *Canada*: feeds its assessments into the OECD Screening Information Data Set (SIDS) and WHO Concise International Chemical Assessment Documents (CICAD) program
- *US*: HPV program assessments are fed into the OECD SIDS program, and the ATSDR and IRIS schemes feed into the CICADs program
- *Current EU scheme*: feeds its assessments into the OECD SIDS program

Additionally, the Canadian scheme routinely uses assessments of other overseas regulatory programs at the categorisation stage to determine human and environmental exposure.

## ATTACHMENT 1.1 – CANADIAN EXISTING SUBSTANCES

### Legal Framework

The *Canadian Environmental Protection (CEPA) Act 1988* provides for the protection of the environment and of the health of Canadians from toxic substances and other pollutants. Under the Act, a substance is considered 'toxic' if it is entering, or may enter, the environment in a quantity or concentration or under conditions that:

- have - or may have - an immediate or long-term harmful effect on the environment or its biological diversity
- constitute - or may constitute - a danger to the environment on which it depends, or
- constitute - or may constitute - a danger to human life or health.

One of the initiatives under CEPA is the Priority Substances Assessment Program (PSAP). The assessment of substances on the Priority Substances List (PSL) provides an in-depth analysis of potential risks to human health and the environment posed by environmental contaminants. A Priority Substance may be a chemical, a group of chemicals, effluents or wastes.

There have been two PSLs (PSL1 and PSL2), which were established from the first CEPA, enacted in 1988. These lists were established by the Ministers of Health and Environment, based on the recommendations from the Ministers' Expert Advisory Panel.

The Act was amended in 1999 (CEPA, 1999). The revised legislation requires systematic categorisation and, if necessary, screening of substances on the Domestic Substances List (DSL). The aim is to speed up the assessment and selection of priority existing substances in Canada, and to set firm deadlines for action to control toxic substances.

The responsibility for assessing Priority Substances is shared by Health Canada and Environment Canada. Health Canada assesses the risks to human health from environmental exposure (non-occupational) to Priority Substances. Environment Canada assesses the risks to the environment and non-human organisms. No occupational health and safety assessment is conducted under the Canadian scheme.

### Inventory

An existing substance is defined as a substance on the DSL. DSL includes all substances manufactured in or imported into Canada in a quantity >100 kg/calendar year, and those substances in Canadian commerce or used for commercial manufacturing between 1 January 1984 and 31 December 1986. DSL currently contains approximately 23 000 substances. The purpose of DSL was to define what was 'New to Canada' and it has been amended from time to time.

### Operations

The risk assessment of existing substances involves the following activities:

1. Identification of candidates for risk assessment
2. Data collection to support priority setting
3. Setting priorities for assessment
4. Conducting the risk assessment
5. Risk management.

#### 1 Identification of candidates

The basis for the identification of candidates for risk assessment include:

- Categorisation and screening of DSL
- Provincial or international decisions – identify and review decisions on prohibited or substantially restricted substances from other jurisdictions
- Public nominations – people can write to the Minister requesting that a substance be added to PSL.

The current focus of the Canadian program is the categorisation and screening of DSL.

#### 2 Data collection for categorisation and screening of DSL

Data sources for human exposure can be obtained from release/emissions (National Pollutant Release Inventory – NPRI), surveys in the provinces, quantity and use codes from DSL (currently being updated), fugacity modelling (to estimate environmental exposure), physico-chemical properties data and US data, if available.

The information necessary to determine environmental effects is sought from published scientific journals and databases, international reports, computer modelling (TOPKAT, ASTER or OASIS), and through direct contact with stakeholders. Very little experimental data are available for environmental endpoints, therefore, QSAR is used mainly to populate the database and complement all experimental and analogue data available.

Other factors considered in categorisation decisions include weight of evidence, model limitations, data validation, comparison with data analogues and, for empirical data, the reliability of the test method, relevance of the data, and adequacy of the data are also considered.

### 3 Setting priorities for assessment

The new process of categorising and screening of substances on DSL is expected to identify most of the candidates for assessment in the future. Under the CEPA (1999), each of the substances on the DSL must be categorised by September 2006 with subsequent screening and full assessment, where warranted, to determine whether the substances are toxic or capable of becoming toxic as defined in the Act.

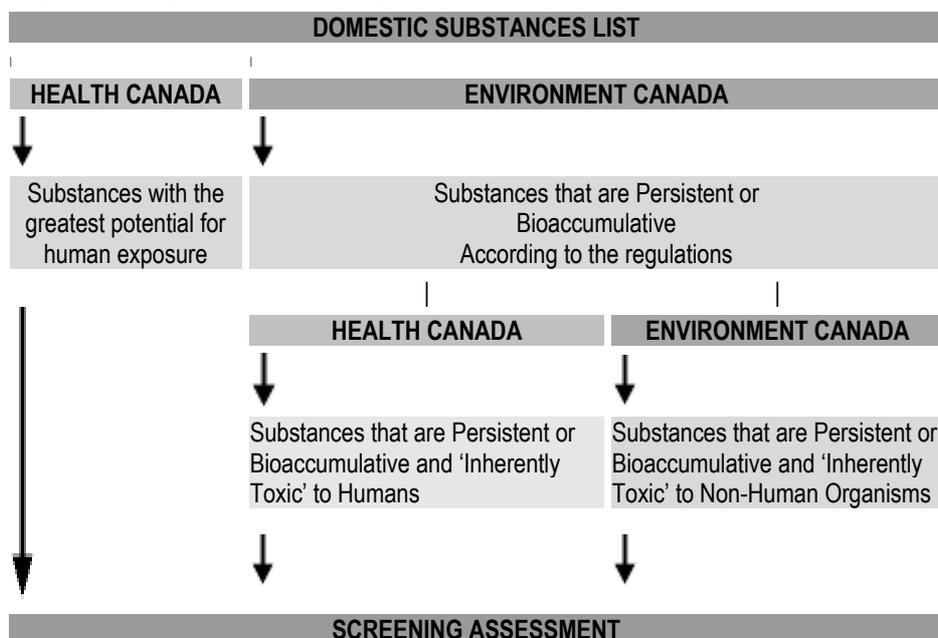
Categorisation and screening are intended for 'grandfathered' substances only (these are substances notified in Canada between 1984-1986). Substances on the DSL are categorised according to the following criteria:

- substances with greatest potential for exposure of the general population, or
- substances that are persistent, bioaccumulative and inherently toxic (PBiT) to humans and non-human organisms.

The approaches to the categorisation of DSL consist of iterative steps including, calls for relevant information, internal and external peer review and public review. If a substance does not meet the above criteria, then no further action is required. A survey is conducted to determine human exposure. Data requested in the survey include volume and use codes, which are used as a surrogate number to rank for exposure.

Endpoints on which substances will be categorised on the basis of 'inherent toxicity to humans' include: carcinogenicity; genotoxicity; developmental toxicity; reproductive toxicity; repeated dose and acute toxicity. Predictions based on QSAR, published assessments and open literature are being developed and tested. The cut-offs of persistence, bioaccumulation potential and inherent toxicity to non-human organisms were set out in the guidance document, *Environment Canada's Guidance for Categorising Organic Substances on the DSL*, which was published in March 2002.

**Figure 1. Categorisation of existing substances on the domestic substances list**



Screening assessments are conducted on substances identified from the categorisation of DSL and those substances reviewed by other jurisdictions. Screening involves a comparison of exposure and effect, and a very limited consideration of weight of evidence and mode of action. The screening assessment is considered as the second stage of prioritisation for a more in-depth risk assessment.

Data considered for screening may include volume of production, releases resulting from its production, processing, uses and disposal, known environmental concentrations of a substance, and environmental fate on the basis of intrinsic physical/chemical properties, environmental mobility and persistence. There is no mandated deadline for the completion of the screening assessment.

There are three possible outcomes of the screening assessment:

- to take no further action on the substance
- to add the substance to the PSL for a more in-depth risk assessment, or
- to recommend that the substance be added to the List of Toxic Substances in Schedule 1 of CEPA. Substances on Schedule 1 can be considered for regulatory or other controls, or added to the Virtual Elimination List.

The result of the screening assessment and a summary of the scientific considerations upon which the proposal is based are published for public comment. A Pilot Project has been initiated to facilitate the screening assessment phase. In the project, 123 substances that meet the categorisation criteria have been identified. Each is currently being assessed to determine whether the substance poses a risk to humans or the environment.

#### **4 Conducting risk assessment**

The approach to health risk assessment is described in the 'Human Health Risk Assessment for Priority Substances' document (Health Canada, 1994) and for environment in the 'Administrative Policy and Process for Conducting Environmental Risk Assessments for Priority Substances' (Environment Canada, 1997).

A draft report is made available for a 60-day public comment period. Following consideration of comments received, the Assessment Reports are revised as appropriate and published with final conclusions as to whether or not the substances are considered to be 'toxic'. The conclusions of each assessment are reported in the Canada Gazette and documented in a report that is available to the public. In addition, several documents, such as fact sheets and scientific journal articles, are published or made available electronically.

When the assessment has been completed, the substance is removed from PSL. The possible outcomes of the PSL assessment are: a) toxic and b) not considered to be toxic. Toxic substances are added to the List of Toxic Substances or may be reviewed for options for controlling risk to human health and/or the environment. The designation of a substance as 'toxic' does not necessarily mean that controls will be imposed. Decisions on the control of substances can only be made in a subsequent risk management phase that includes considerations of the risks and benefits associated with the continued use of the substance, eg. based on subsequent analysis of social, economic and scientific factors.

#### **5 Risk management**

If a substance is found to be 'toxic,' the federal government works with the provinces, territories, industry, non-government organisations and other interested parties to develop a management plan to reduce or eliminate the harmful effects of the substance both on the environment and the health of Canadians. Controls may include regulations, pollution prevention plans, environmental performance agreement and guidelines and codes of practice. Options for controlling exposure to 'toxic' substances are done in consultation with stakeholders.

#### **References**

Environment Canada (1997). Administrative Policy and Process for Conducting Environmental Risk Assessments for Priority Substances. Minister of Public Works and Government Services, Ottawa, Canada.

Existing Substances Branch. Available at: <http://www.ec.gc.ca/substances/ese/eng/esehome.cfm>. Accessed 4 February 2003.

Existing Substances Division. Available at: <http://www.hc-sc.gc.ca/hecs-sesc/exsd/index.htm>. Accessed 17 January 2003.

Health Canada (1994). Human Health Risk Assessment for Priority Substances. Minister of Public Works and Government Services, Ottawa, Canada.

Industry Coordinating Groups (ICG) for CEPA (2002). CEPA Update Conference, 9-10 October 2002, Toronto, Canada.

## ATTACHMENT 1.2 – NEW ZEALAND EXISTING CHEMICALS LEGISLATION

### Overview

The hazardous substances part of the New Zealand HSNO Act for came into effect in New Zealand in July 2001. It is an approval-based scheme, with all hazardous substances (single entities and products) required to be listed on the Register.

All existing substances will be assigned a classification that reflects the type and degree of its hazard. Substances determined to be hazardous according to criteria will be transferred to the Register. The regulations then provide the controls that apply as a result of that classification. The classification system in New Zealand is similar to the UN Globally Harmonised System for Classification and Labelling (GHS).

### Legal framework

Hazardous Substances and New Organisms (HSNO) Act 1996

The hazardous substances part of the *Hazardous Substances and New Organisms (HSNO) Act 1996* began on 2 July 2001. This legislation repealed and amended a number of pre-existing Acts relating to dangerous goods, toxic substances, explosives, pesticides, animal remedies and others.

### Existing Chemical lists

Two databases exist at ERMA NZ and these are the Notified Toxic Substances (NOTS) database contains 217 000 entries (including both single substances and mixtures) and the Register.

The NOTS database is a 'temporary' database, with its substances currently being transferred as Approved Substances to the Register via the Transfer Process (due for completion in 2006).

The Register is a public database that contains all approved hazardous substances (both new and existing) with HSNO classifications and controls (labelling, packaging, exposure limits etc). Each substance will have a unique identification number (HSNO Approval Number).

### Transfer of Existing Chemicals

Existing substances are divided into two groups:

- *Assessed substances* - substances that have been assessed and approved under previous legislation within NZ before HSNO Act commenced, and
- *Notified toxic substances (NOTS)* - substances that have been notified (but not assessed) under section 32 of the Toxic Substances Act.

For a substance to be an existing substance, it had to be notified to ERMA NZ before the commencement of the hazardous substances part of the HSNO Act. These notifications have been entered into the NOTS database.

The information required was the identity of single substances and compositional details for all mixtures including identification of all the components and their percentages.

The process of 'Transfer' involves assigning hazard classifications and controls from the HSNO Act framework to the existing substances. The definition of hazardous lies within the *HSNO Act 1996 Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001*. In the determination of 'hazardous' the following properties are considered: explosiveness, flammability, oxidising capacity, corrosiveness, toxicity and ecotoxicity.

Substances will be classified using information from existing assessments and any new information and application of the classification criteria. Assessed substances determined to be hazardous are transferred to the Register.

Once the hazard classification is complete, controls are automatically assigned. Each classification has a suite of controls designed to prevent any adverse effects caused by the intrinsic hazards of the substance. Controls set under the HSNO Act include the full lifecycle controls (packaging, labelling, disposal etc), occupational (including tolerable exposure limits; TELs) and environmental controls (including environmental exposure limits; EELs).

It is estimated that the NOTS database will be sorted from the 217 000 entries (as at June 2003) to approximately 70 000 substances. Sorting will identify non-hazardous substances; duplicate notifications; obsolete products and substances already assessed. Grouping will further reduce numbers of substances requiring transfer.

## Reassessments

The HSNO Act also provides for the reassessment of substances. Reassessments are where the risks and benefits of a substance are reconsidered. Reassessment may be necessary if:

- New information about the effects of the substance becomes available, or
- Its use is changed significantly, or
- Alternative (less hazardous) substances have become available.

In addition, as the Transfer of Substances occurs, it is envisaged that a number of substances will be identified during the comparison of controls process that indicate a more detailed investigation of the substance is required.

For reassessments the public, the Minister, an organisation/association or the Chief Executive of ERMA NZ can nominate a substance for reassessment or ask for a reassessment. ERMA NZ maintains a priority list of potential reassessments. Reassessments may be paid for by sponsors (individuals, companies or organisations) or ERMA. In addition, for a reassessment to occur grounds for reassessment must be supplied to ERMA with supporting information. The timeframe and cost of reassessment is dependent on the quantity and quality of information available, issues raised and general length of review for the substance or group of substances.

The outcome of a Reassessment could range from no action required to withdrawing the existing approval on the substance therefore making its use, manufacture and importation illegal. In addition, when new information not only suggests a reassessment is justified, but indicates that continuation of the existing approval could be deleterious, ERMA can suspend the existing approval while the reassessment is conducted. Reassessment reports will be available to the public on the Register.

One industrial chemical, methylated spirits, was undergoing reassessment. The reasons given for the reassessment included the inherent risks of the substance given its pattern of use, the extent to which the existing management regime is achieving effective management of the risks and the level of public concern.

When the Transfer of Substances is completed, the reassessment work is expected to increase. Resources will be transferred from the Transfer of Substances Group to the area of Reassessments, therefore changing the focus from a hazard assessment program into a risk assessment program.

## Other programs

ERMA NZ also maintains an Incidents Database. This database holds reported incidents filed by first response agencies and newspaper reports involving hazardous substances. This information will be used to prioritise reassessments.

## References

ERMA New Zealand Transfer of Substances Homepage:  
<http://www.ermanz.govt.nz/TransferOfSubstances/Index.htm> (Accessed 26/02/03)

ERMA New Zealand Hazardous Substances Homepage:  
<http://www.ermanz.govt.nz/HazardousSubstances/index.htm> (Accessed 26/02/03)

ERMA New Zealand Quick Guide to the Transfer of Substances, at:  
<http://www.ermanz.govt.nz/Publications/pdfs/ER-QG-20-2.pdf> (Accessed 26/02/03)

Hazardous Substances and New Organisms Act Homepage: <http://www.hsno.govt.nz/> (Accessed 26/02/03)

## ATTACHMENT 1.3 – CURRENT EU SYSTEM FOR EXISTING CHEMICALS

### Overview

The EU Existing Chemicals Regulation (ESR) program undertakes risk assessment and risk management activities on a priority basis. Industry is required to provide data sets which are then assessed by the regulatory authorities and risk reduction strategies implemented if required. To date, approximately 45 risk assessments have been completed.

### Legal framework

Council Regulation (EEC) 793/93 (Existing Substances Regulation) came into force in 1993. The Regulation was intended to complement the already existing rules governed by Council Directive 67/548/EEC for new chemical substances.

### Inventories

An 'existing' chemical substance in the EU is defined as any chemical listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). EINECS is a closed inventory of 100 195 chemical substances that were deemed to be on the European Community market between 1971 and 1981. Information includes chemical name, CAS number, EINECS number and molecular formula (if possible).

### Operation

The evaluation and control of the risks posed by existing chemicals is carried out in four steps, described below.

#### 1 Data collection

The Regulation was initially concerned with High Production Volume Chemicals (HPVCs) that were defined as substances imported or produced in quantities exceeding 1000 tonnes per year between 1990 and 1994. Substances imported or produced in quantities between 10 and 1000 tonnes per year are deemed Low Production Volume Substances (LPVCs). A reduced data set can be submitted for LPVCs. Data for HPVCs had to be submitted by June 1995 and by June 1998 for LPVCs.

Data is submitted using the Harmonised Electronic DataSET (HEDSET) software program, and is managed by the International Uniform Chemical Database (IUCLID). Data required in the HEDSET includes: name of the substance, produced and/or imported quantities, classification and labelling information, and reasonably foreseeable uses. However, for HPVCs data in the following areas are also to be submitted: physico-chemical properties, information related to chemical fate and pathways, and toxicological and ecotoxicological properties.

All companies that have submitted a dataset are required to update the information at least every three years. The update should include, where appropriate, new uses that substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance and new data on physicochemical properties, toxicological or ecotoxicological effects.

An evaluation of the ESR program completed in May 2002 shows that for the data in IUCLID, 14% of the HPVCs have data at the level of the base-set, 65% have less than base-set and 21% have no data. This indicates that there are considerable data gaps for HPVCs.

#### 2 Priority setting

In order to handle the mass amount of information in IUCLID, HPVC chemicals are ranked and scored using the EU Risk Ranking Method (EURAM). EURAM calculates scores for human health and the environment using a simple exposure-effect model, though the method for calculation is complex. Environmental ranking is based on: environmental exposure, emissions, distribution (into the different environmental compartments), degradation and results in an environmental combined exposure and effects score. Human health ranking is based on: human health exposure, distribution, human health scoring (using the R phrases, the test results from genetic toxicity and reproductive toxicity, and the presence or absence of test results for repeated dose toxicity) and results in a human health combined exposure and effects score (for a comprehensive evaluation of EURAM see Hansen *et al.*, 1999).

The results of the EURAM form the basis for discussions between Member States, Industry and NGOs on selecting substances for a Working List. Industry is encouraged to include, as a high priority, substances on the Working List in the OECD's High Production Volume Existing Chemicals Program. By doing so, HEROs (High Expected Regulatory Outcome substances) can be better identified and possible NEROs (No Expected Regulatory Outcome substances) can be removed from the working list if convincing evidence is brought forward by industry. A working list of national priorities is also developed.

Using Expert Judgement the Commission combines these two lists, in consultation with Member States, to one EU priority list. Factors taken into account when drawing up the priority list include: the effects of substance to man or the environment, the exposure of man or the environment to the substance, the lack of data on the effects of the substance on man and the environment, work already carried out in other fora, and other Community legislation and/or programmes relating to dangerous substances.

The working list is updated regularly in line with the preparation of regular priority lists. Companies must submit information on priority chemicals to IUCLID within six months of publication of the list. Since 1994, four priority lists have been published containing a cumulative total of 141 substances (as at end 2003).

### **3 Risk assessment**

Member states (the rapporteurs) nominate themselves to be responsible for evaluation of chemicals on the priority list. Substances must undergo an in-depth risk assessment covering the risks posed by the priority substance at each stage of the chemical's lifecycle, to man (workers, consumers and man exposed via the environment) and the environment (the terrestrial, aquatic, and atmospheric eco-systems and accumulation through the food chain).

The evaluation of the priority substance consists of four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterisation. The risk assessment is conducted following the EU Technical Guidance Documents (TGD) on Risk Assessment for New and Existing Substances.

Exposure of humans from all relevant sources is considered, ie. workplace, consumer products, air, food and drinking water. Each exposure scenario is assessed individually, and where appropriate, an overall combined exposure is also estimated.

Industry is obliged to submit to the rapporteur all relevant available information and corresponding study reports for the substance concerned. If a minimum data set is not available to start identifying the hazards the regulation allows further tests to be requested where there are causes for concern.

Draft risk assessments are distributed to other Member States for comment prior to Technical Meetings and mediated by the Commission, which attempts to reach consensus on the conclusions of the risk assessment. After adoption of the risk assessment three publications are produced:

- the comprehensive risk assessment report (as a book and on the ECB website)
- a summary thereof (as an EUR report and on the ECB website), and
- a listing of the conclusions in the Official Journal of the EC.

### **4 Outcomes**

If a risk cannot be ruled out, then the rapporteur also has to propose a Risk Reduction strategy utilising the Technical Guidance Document on Risk Reduction. Controls can include, emission controls at industrial sites, marketing and use restrictions, or revision/introduction of occupational exposure standards or environmental quality objectives.

#### **Other Existing Chemical activities**

Substances evaluated in the ESR program are brought before the EU Working Group on Classification and Labelling of Dangerous Substances for discussion. Substances are classified in accordance with Directive 67/548/EEC as amended by Directive 2001/59/EC for several end-points concerning physical-chemical properties, health or environmental effects.

Substances are then proposed for entry to the list of harmonised classifications of substances, Annex I to Directive 67/548/EEC, which is legally binding. These regulations also cover classification of consumer products placed on the market containing hazardous substances.

#### **References**

Bodar CWM, Berhault, F, de Bruijn JHM, van Leeuwen CJ, Prank MEJ and Vermeire TG. Evaluation of EU Risk Assessments Existing Chemicals (EC Regulation 793/93). RIVM Report 601504002/2002. Available at: <http://ecb.jrc.it/existing-chemicals/> Accessed 6/2/2003.

Classification and Labelling. Available at: <http://ecb.jrc.it/classification-labelling/> Accessed 6/3/2003.

Existing Chemicals. Available at: <http://ecb.jrc.it/existing-chemicals/> Accessed 6/2/2003.

Hansen B.G, van Haelst A.G, van Leeuwen K and van der Zandt P (1999). Priority setting for existing chemicals: European Union Risk Ranking Method. *Environ. Tox. and Chem.*, 18 (4), 772-779.

## ATTACHMENT 1.4 – PROPOSED EU SYSTEM FOR CHEMICALS (REACH)

### Overview

The proposed EU Chemicals system will require companies to register all new and existing chemicals imported or manufactured at > 1 tonne/year and provide a base set of data. The amount of data initially required will depend of the volume of the chemical imported and/or manufactured. The authorities will then evaluate higher volume chemicals and chemicals of concern. Chemicals that pose a risk may be subject to authorisation for use or restrictions. There are also requirements for downstream users to provide information on use and risk management measures.

### Background

In recent years the European Commission in consultation with member states, industry, environmental and consumer NGOs as well as representatives from applicant countries has reviewed its chemical policy program. One of the major problems identified was that there is a general lack of knowledge about the properties and the uses of the majority of existing substances (which are not subject to the same testing requirements as new chemicals).

Current legislation only requires the manufacturers and importers of substances to provide information, but not the downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about exposure arising from downstream uses is generally scarce. The current existing chemicals risk assessment process is also slow and resource intensive.

Consultations resulted in the European Commission publishing, in February 2001, a White Paper setting out the strategy for a future Policy for Chemicals. Key elements of the proposed new strategy are:

- a single regulatory framework which provides equivalent knowledge about the hazards of substances marketed before and after September 1981 (new and existing substances) and their uses, in order to provide coherence in the level of protection
- reversal of responsibility from authorities to industry for testing and risk assessment of chemicals
- promotion of innovation and competitiveness without compromising the high level of protection
- introduction of a tailor-made authorisation system where stringent control is ensured for the most dangerous substances, and
- increased transparency and information about chemicals.

The draft legislation was released for consultation in April 2003.

### Proposed EU chemicals strategy (REACH)

The Commission proposes that existing and new substances should in the future be subject to the same procedure under a single system. The proposed system is called REACH, for the Registration, Evaluation and Authorisation of Chemicals.

**1 Registration** of basic information for all existing and new substances exceeding a production volume of one tonne to be submitted by companies in a central database.

Information to be submitted for registration purposes includes:

- identity of the registrant(s)
- identity of the substance
- summary of the intrinsic properties, ie. physicochemical properties, toxicity and ecotoxicity data requirements, based on tonnage
- the proposed classification and labelling with justification
- a statement as to whether or not information has been generated by testing on vertebrate animals, and
- a safety assessment so called 'Chemical Safety Report', containing information on risk management measures, the safety assessment that led to the choice of these measures and the information on which the assessment is based.

Information requirements are modulated by tonnage as this gives an indication of the potential for exposure.

Proposed deadlines for registration are from date the regulation comes into force:

Substances	Volume threshold*	Deadline (years)
Categories 1 and 2 carcinogens, mutagens and reproductive toxicants (CMRs)	≥ 1 tonne	3
All other substances	≥ 1000 tonnes	3
All other substances	≥ 100 tonnes	6
All other substances	≥ 1 tonne	11

\* tonnes/manufacture or importer/year

## 2 Evaluation of testing proposals and priority chemicals as follows:

- *Standard evaluation of Testing Proposals:* requires EU authorities to examine testing proposals for substances > 100 tonnes/yr, ie. substances which require additional testing. The aim is to avoid unnecessary testing, and
- *Priority evaluation:* provides a mechanism for a Member EU State to consider whether industry should be required to obtain more information, including to perform further testing on the basis of the aggregated tonnage (by several registrants) during registration, further testing where there are concerns, more information on uses and support for any justifications. While authorities are expected to concentrate their efforts on high volume substances or those with properties of concern (eg. CMRs and PBT chemicals), priority evaluation can also consider randomly selected substances, in order to give confidence that all registrations meet the information requirements of the registration provisions.

**3 Authorisation** of substances of very high concern before they can be used for a particular purpose, marketed as such or as a component of a product. These are substances that are either, carcinogenic, mutagenic or toxic to reproduction (CMRs classification categories 1 and 2), persistent organic pollutants (POPs) or other substances demonstrated to be of equivalent level of concern, such as endocrine disruptors.

An authorisation will be granted if the risks (health and environment) from use of a substance are adequately controlled and also if the socio-economic benefits outweigh the risk to human health and/or the environment. In particular, all of the followings will be taken into consideration:

- the risk posed by the uses of the substance
- the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interest parties, and
- any available information on alternative substances or technologies. Substitution will be considered, however, the existence of alternatives is in itself insufficient grounds to refuse an authorisation.

Granted authorisations will have to specify to whom the authorisation is given, the substance and authorised use as well as any conditions that apply including a specified review period. Notwithstanding any conditions of an authorisation, the holder must ensure that the level of exposure is reduced to as low as technically possible. Also, holders of an authorisation must include the authorisation number on any label for a substance so that downstream users will be able to check the conditions of authorisation available on the Agency website.

In addition, any substance may be subject to Restrictions. Restrictions may be either conditions for manufacture, use(s) and/or placing on the market or prohibitions of any of these activities.

### Obligation for downstream users to report information

Before commencing a particular use of a registered substance, downstream users are obliged to assess the safety of their uses of substances and to take appropriate risk management measures, especially in the following cases:

- if the downstream user is using a substance in a manner not covered by a manufacturer or importer's chemical safety report (CSR, including incorporating it into an article), and
- if the downstream user applies or recommends different risk management measures.

The CSR provided by the supplier may be used as the basis for their safety assessment for intended uses while developing the necessary elements of the assessment targeted on unintended uses, ie. uses not covered in the supplier' safety assessment report.

The information reported by the downstream user must include the following:

- identity and contact details
- identity of the substance
- if known, the identity of the manufacturer(s) or the importer(s)
- a brief description of the use(s), and
- a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his/her chemical safety assessment.

Downstream users of substances < 250 kg/year have no reporting obligation. The volume threshold for reporting ensures that the obligations are proportionate with the risk. Note, however, that the obligation to perform a risk assessment still applies below this threshold as for all substances.

Downstream users may use a substance for an authorised use providing they obtain the substance from a company for whom an authorisation has been granted and that they keep within the conditions of that authorisation. These downstream users must notify the Agency within 3 months of the first supply of the substance.

#### **Information through the supply chain**

All members in the supply chain must communicate information down the supply chain including:

- the safety data sheet
- the chemical safety report
- the registration number (under REACH)
- authorisation requirements
- restrictions imposed
- any other risk management information.

The information must be communicated, at latest, at the time of the first delivery of a substance following the entry into force of the Regulation. The information must be updated if new information or requirements, eg. authorisation and restrictions change. Workers must be granted access to the information. Information must also be communicated up the supply chain. Information must also be supplied to distributors and given to immediate downstream users and distributors as appropriate.

#### **References**

New Chemicals Legislation – REACH, at:

<http://www.europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm>, Accessed 20/7/2003

Commission of the European Communities. White Paper – Strategy for a future Chemical Policy. COM (2001) 88 final. Available at: <http://www.europa.eu.int/comm/environment/chemicals/whitepaper.htm>

Press Release – Commission sets out the path towards sustainable use of chemicals. 13 February 2001. (IP/01/201). Available at: <http://www.europa.eu.int/rapid/start/cgi/guesten.ksh>, Accessed 19/2/2003.

## ATTACHMENT 1.5 – US EXISTING CHEMICALS PROGRAMS

There is no single chemical assessment scheme in the US. Instead there are several organisations that evaluate existing chemicals. This overview has focused on the activities of the US Environmental Protection Agency (US EPA), which oversees assessment schemes such as the Integrated Risk Information System (IRIS), Voluntary Children's Chemical Evaluation Program (VCCEP), Persistent, Bioaccumulative and Toxic (PBT) chemical program and High Production Volume (HPV) program, and the US Department of Health and Human Services, which runs schemes such as the Agency for Toxic Substances and Disease Registry (ATSDR).

### A. US Environmental Protection Agency

#### Legislation

The Office of Pollution Prevention and Toxics (OPPT) within the US EPA is responsible for managing the Existing Chemical Program under the *Toxic Substances Control Act 1976* (TSCA).

#### Inventory

An existing chemical is defined as a chemical in the TSCA Chemical Substances Inventory. This is not a closed inventory, as substances have been added to it. Chemicals are added to the inventory on receipt of Notice of Commencement (NOC) from manufacturers or importers.

As part of the US EPA's new chemical notification process, manufacturers and importers of a new chemical are required to notify the agency, via NOC that they have commenced introducing the chemical. All industrial chemicals in commerce between 1975 and 1977 were 'grandfathered' onto the inventory. Since 1986, at four-year intervals (under the Inventory Update Rule) substances included on the inventory have to be updated with companies providing information on the production volume, plant site and site-limited status of these substances.

#### Existing Chemicals program outline and its outcomes

The US EPA's Chemical Information and Testing Branch (CITB) estimated that of the 70 000 chemicals on the TSCA inventory approximately 15 000 are in commerce at this time. The methodology used to determine the number of substances is not available.

The US Existing Chemicals program tends to be reactive rather than proactive. This is primarily due to the legislation, which requires a case to be made to prove that information is required. The Existing Chemical Program focuses on the HPV chemicals, and high profile chemicals such as asbestos, lead, and PCBs.

For those chemicals, which pose a problem, the EPA has a number of means by which they can reduce the risks. These include:

- limit or prohibit use
- voluntary agreements, alone or in combination with local, regional, federal or state regulatory approaches
- dissemination of risk management information to assist the selection of safer substitutes; emphasis on pollution prevention, and innovative control technology to reduce exposure and environmental release, and
- use of chemical emission data from specified industry groups and federal facilities on the annually updated Toxic Release Inventory, to address site-specific chemical concerns; refined risk assessment and cost/benefits analysis; and challenge industry Product Stewardship and Responsible Care goals.

#### Other programs managed by the EPA

Four chemical programs managed by the EPA are the Integrated Risk Information Systems (IRIS), Persistent, Bioaccumulative, Voluntary Children's Chemical Evaluation Program (VCCEP), Toxic Pollutants Strategy (PBT Strategy), and the High Production Volume (HPV) Challenge Program.

#### Integrated risk information system (IRIS)

IRIS is an electronic database developed (and maintained) by the EPA containing summaries of human health assessments.

The database contains quantitative and qualitative information on selected chemicals, including hazard identification and dose-response assessment information. Combined with specific exposure information, the data in IRIS can be used for characterisation of the public health risks of a given chemical in a given situation that can then lead to risk management decisions.

EPA develops a list of substances for IRIS assessment on an annual basis. Chemicals are selected based on one or more of the following factors:

- agency statutory, regulatory, or program implementation needs
- the availability of new scientific information or methodology that might significantly change current IRIS information
- interest to other levels of government or the public, and
- most of the scientific assessment work has been completed while meeting other Agency requirements, and only a modest additional effort will be needed to complete the review and documentation for IRIS.

#### **Voluntary children's chemical evaluation program (VCCEP)**

In December 2000 the EPA announced the VCCEP that is intended to provide data to enable the public to understand the potential health risks to children associated with certain chemical exposures. The VCCEP consists of 3 tiers of data that a sponsor could commit to separately.

In a pilot program, the EPA asked companies that manufacture and/or import 23 specific chemicals found in human tissues (ie. blood, breast milk and exhaled breath) and the environment (ie. indoor air or drinking water) as an unregulated contaminant in various monitoring programs to volunteer to sponsor their evaluation in Tier 1. Thirty-five companies and ten consortia responded and volunteered to sponsor 20 chemicals in the VCCEP Pilot. Information was requested on both hazard (human health effects) and exposure. For health effects, information is submitted in three tiers with the Tier 1 tests being the same as those requested in the HPV Challenge Program. Information submitted by the sponsor will be evaluated and the EPA will determine whether additional higher tier information is needed.

#### **Persistent, bioaccumulative and toxic (PBT) chemical program**

In 1998, the EPA released its agency-wide multimedia (environmental) strategy for Priority PBTs. The four main elements of the EPA's strategy are:

- develop and implement national action plans to reduce PBT pollutant, utilising all the tools available to the EPA
- continue to screen for and select more priority PBT pollutants for action
- prevent new PBTs from entering the marketplace, and
- measure progress of these action plans against government and national performance indicators.

The action plans mentioned above will use regulatory action where voluntary action is deemed insufficient. The action plans will consider enforcement and compliance, international coordination, place-based remediation of existing PBT contamination, research, technology development and monitoring, community and sector-based projects, the use of outreach and public advisories, and possible integration of efforts across chemicals. Action plans for 12 PBTs are in development or have been published.

#### **High production volume (HPV) challenge program**

In 1998, the US EPA announced its HPV Challenge Program. The program aims to make publicly available a complete set of baseline health and environmental effects data on HPV chemicals.

There are 2800 chemicals on the HPV Chemical List. The list was developed on data reported to EPA as part of its Inventory Update for 1990. It was updated following the 1994 Inventory Update. HPV chemicals are defined as those manufactured in or imported into the US in amounts equal to or exceeding 1 million pounds per year.

The Program is a voluntary chemical testing effort, in which US EPA works in partnership with industry and environmental groups. Data are collected for all chemicals on the EPA's List of HPV Chemicals. Additional testing will be necessary only when the existing data are inadequate. The program is carried out in a manner consistent with the protocol for the OECD's SIDS Program. This ensures that the US is able to fulfil its international obligations and conversely allows the data from SIDS testing and assessments to be used in the HPV Challenge Program.

## **B. U.S. Department of Health and Human Services**

### **The agency for toxic substances and disease registry (ATSDR)**

The ATSDR is an agency of the U.S. Department of Health and Human Services (DHHS) and was created to implement the health-related sections of the *Comprehensive Environmental Response, Compensation, and Liability Act* of 1980 (CERCLA). The ATSDR also has responsibilities under the *Conservation and Recovery Act* of 1976 (RCRA) as amended, and *Superfund Amendments and Reauthorisation Act* of 1986 (SARA).

### **Toxicological profiles**

The ATSDR produces a list of priority substances, called the CERCLA Priority List of Hazardous Substances. Each substance on this list is a candidate to become an ATSDR toxicological profile. The ranking of hazardous substances on the priority list is based on the three criteria, which are combined to result in the total score. The three criteria are:

- frequency of occurrence at National Priorities List sites: ATSDR's HazDat database is the source of data for the frequency of occurrence of substances at National Priority List hazardous waste sites or facilities
- toxicity, and
- potential for human exposure: based on two parts, the concentration of the substance in environment media, and the exposure status of the populations. HazDat serves as the source of this information.

ATSDR toxicological profiles characterise the toxicologic and adverse health effects information for the hazardous substance. Peer reviewed by government scientists, a non-government panel and the public, these profiles identify and review the key literature for toxicologic properties. Although other significant literature is presented it is described in less detail. Data needs are also identified that are of significance for the protection of public health.

The ATSDR profiles are used to derive minimum risk levels (MRL). A MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health over specified duration of exposure. Inhalation and oral MRL are determined. Dermal MRL are currently not available.

Other products are Public Health Statements (PHSs) and ToxFAQ, which are taken from their respective ATSDR Toxicological Profiles. Each Public Health Statement serves as a summary for that complete Toxicological Profile. The PHSs provide information in a question and answer format which address the most frequently asked questions about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health. The ATSDR ToxFAQs are summaries about hazardous substances based on the ATSDR Toxicological Profiles and Public Health Statements. Each fact sheet serves as a quick and easy to understand guide. Answers are provided to the most frequently asked questions (FAQs) about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

### **Other programs managed by the US DHHS**

Three chemical programs managed by the DHSS are the National Toxicology Program (NTP), Centre for the Evaluation of Risks to Human Reproduction (CERHR) and the Report on Carcinogens (RoC).

### **National toxicology program (NTP)**

In 1978 the US HHS established the NTP to coordinate toxicological testing within the Department. The NTP is an interagency program, and its mission is to evaluate the agents of public health concern by developing and applying tools of modern toxicology and molecular biology.

### **Centre for the evaluation of risks to human reproduction (CERHR)**

The NTP and the National Institute of Environmental Health Sciences established the CERHR in 1998 to provide uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. Independent panels of experts from academia, industry, government research and regulatory agencies:

- evaluate the evidence that the chemical is a potential hazard to human reproduction or development
- determine patterns of chemical use and human exposure, and
- reach a consensus on the potential human reproductive and developmental health hazard and identify needs for additional research/testing to improve the scientific certainty of a chemicals hazard or risk.

### **Report on carcinogens (RoC)**

The RoC, which is published biennially by the DHHS, is a scientific and public health document that identifies and discusses substances that may pose a carcinogenic hazard to human health. The document is a compilation of data on:

- carcinogenicity, genotoxicity, and mode of action listed in humans and/or in animals
- potential for human exposure to the substance, and
- federal regulations to limit exposure.

The RoC does not present quantitative assessments of the carcinogenic risk of the substance, as these are the responsibility of other agencies.

### References

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US EPA Integrated Risk Information System. Available at: <http://www.epa.gov/iris/intro.htm> Accessed 07/02/03

US EPA Voluntary Children's Chemical Evaluation Program. Available at: <http://www.epa.gov/chemrtk/vccep/index.htm> Accessed 07/02/03

US EPA Persistent, Bioaccumulative and Toxic Chemical Program. Available at: <http://www.epa.gov/opptintr/pbt/fact.htm> Accessed 19/03/03

US EPA High Production Volume Challenge Program. Available at: <http://www.epa.gov/opptintr/chemrtk/volchall.htm> Accessed 07/03/03

Agency for Toxic Substances and Disease Registry. Available at: <http://www.atsdr.cdc.gov/2002-2007strategicplan.html> Accessed 28/02/03

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National Toxicology Program and Report on Carcinogens. Available at: <http://ntp-server.niehs.nih.gov/> Accessed 17/03/03

## APPENDIX 2: ABOUT THE NICNAS EXISTING CHEMICALS ASSESSMENT PROGRAM

The Existing Chemicals Program is a program of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which was established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act). Funding of the Program is 100% cost recovered through company registration fees.

### Priority Existing Chemical (PEC) assessments

The most well known activity of the Program is the assessment of chemicals known as Priority Existing Chemicals (PECs). PEC assessments are legislated under the Act, and have legislated timeframes and consultation and appeal provisions.

As well as full risk assessments, NICNAS can now conduct more focused 'preliminary' assessments on specified aspects of a chemical, namely, its properties, use or uses, intrinsic adverse effects, and/or the extent to which people or the environment will be exposed to the chemical. Preliminary assessments consider whether a full risk assessment is required for the chemical.

A list of all existing chemicals assessed by NICNAS as at August 2006 is contained in [Attachment 2.1](#).

#### *The Nomination, Screening and Selection of PECs.*

The selection of chemicals to undergo a PEC assessment is based on a process that screens and ranks publicly nominated chemicals of concern. Nominations of chemicals of concern can be made at any time, however to publicise and administratively facilitate nominations NICNAS periodically makes calls for nominations. A publicity campaign for a call for nomination involves advertisements in national newspapers, notices in the *Chemical Gazette* and *NICNAS Matters*, and mail-outs to a target audience of occupational health and safety groups, relevant government authorities, industry associations, workers' health centres, unions, environmental groups and consumer bodies.

Nominated chemicals are screened to determine whether they are indeed industrial chemicals as defined under the Act, and if so, placed on a 'base list' of chemicals. Each chemical on this list is then screened and ranked against a set of criteria covering issues in public health, occupational health and safety, and the environment. Each criterion is indicative of a type of potential hazard to people or the environment and the set of criteria therefore give an overview of the types of hazards usually presented to people and the environment when exposure to the chemical occurs. In addition, the criteria include one for national or international concern to facilitate the responsiveness of the PEC program.

The final list of selected and standby chemicals is known as the Candidate List. Reasons for non-selection of chemicals are documented and reported to the nominators of the chemicals and published on the NICNAS website. The Candidate List is used when considering which chemical(s) to recommend for assessment as PECs. Information obtained through the screening and ranking process, as well as information obtained from industry through notices placed in the *Chemical Gazette*, and any other relevant information is taken into consideration when selecting chemicals as PECs.

#### *Outcomes of PEC assessments*

PEC assessment reports provide information on risks to human health and the environment. Recommendations on ways to control and reduce the risks are made available to companies introducing chemicals, to people in the workplace, to other government agencies, and the public. Recommendations contained in PEC assessment reports are generally directed to three groups: peak agencies and regulatory bodies such as the National Occupational Health and Safety Commission (NOHSC) and the National Drugs and Poisons Schedule Committee (NDPSC); state and territory government authorities; and industry. Examples of the types of recommendations that have been made are detailed in [Attachment 2.2](#).

### Post assessment activities

A significant number of activities undertaken by the Program relate to the post-assessment follow-up of chemicals that have previously been assessed as PECs.

Safety Information Sheets containing the main findings and recommendations of a PEC assessment, written in plain English, are now compiled for all PECs, and disseminated widely to industry, unions and labour councils, and state and territory representatives.

Chemicals that have been assessed as PECs are subject to secondary notification and assessment should significant new data about the chemical or its uses or exposure in Australia become available. Literature searches are conducted regularly and any new data analysed as part of normal post-assessment surveillance. Other post-assessment activities include cooperative projects with industry, unions and/or government authorities on such things as communication strategies related to a particular chemical.

Uptake of PEC recommendations by regulatory bodies, both Commonwealth and State, are followed up on a regular basis. An evaluation tool for assessing the uptake of recommendations of PEC reports has been developed and tested. The review of the Program will inform any further activities to be undertaken to measure the uptake of recommendations by industry. It is hoped that the evaluation will assist in identifying factors that may be inhibiting uptake of recommendations, and point the way to strategies to improve the outcomes of the PEC Program.

Other Chemical Information Products In recent years, the Program has undertaken the production of chemical information products that are more targeted in their focus than PEC assessments and faster to produce. The chemicals selected are of concern for some reason, may or may not be on the PEC candidate list, and have not been declared as PECs. These chemical information products serve to address the situation where there is a need for data on a chemical, but not necessarily for an in-depth evaluation of the data.

High Volume Industrial Chemical List (HVICL) Another output of the Existing Chemicals Program is the compilation of a list of chemicals present in Australia in high volumes, based on information supplied by industry. The initial HVICL was compiled between 1999-2002, and it will be updated regularly. The HVICL contains approximately 300 chemicals that are either imported or manufactured in Australia in quantities  $\geq 1000$  tonnes. The HVICL assists in the screening of chemicals for assessment under the Existing Chemicals Program by providing information on quantities (and therefore potential exposure) of individual chemicals being considered for assessment, and on the pattern of introduction (import and/or manufacture), uses, and industry sectors that it is used in. It also assists in determining Australia's input to the OECD Chemicals Program.

Enquiries The Program provides a telephone and written information service to people with general queries about existing industrial chemicals as well as queries specific to the Program.

### **International harmonisation of the assessment of existing chemicals**

There are two international assessment programs for existing chemicals that coordinate international agreement of chemical assessments, based on draft assessments contributed by participating countries. These programs are the OECD's Screening Information Data Set (SIDS) program, and the International Program on Chemical Safety's (IPCS) Concise Chemical Assessment Documents (CICADS) Program. The SIDS program aims to fill data gaps for existing chemicals produced in high volume in the OECD. CICADS provide summaries of the health and environment effects of a chemical and characterise risk. Australia, via NICNAS, participates in these programs.

Australia has sponsored or co-sponsored chemicals in the SIDS program. All sponsored chemicals to date have been PECs or candidate PECs, thus rationalising the resources required to participate in the program. In addition, NICNAS actively reviews and provides comments on draft assessments submitted by other countries.

Hazard assessments produced under the SIDS program have been used by NICNAS in reviews of chemicals and the production of information sheets on chemicals, as well as in developing risk assessments of PECs. NICNAS representatives participate in the OECD's Existing Chemicals Task Force that policy guidance to the SIDS program.

NICNAS has also contributed to the CICADS program through submission of two documents drawn from PEC assessments.

NICNAS' participation in these programs allows access to existing chemical assessments from many governments for use in the national assessment program, and enables us to contribute to the global effort to assess existing chemicals, including the harmonised development of Australian assessment methodologies with overseas authorities.

## ATTACHMENT 2.1 – CHEMICALS ASSESSMENTS

### A. List of chemicals assessed as PECs

PEC Assessment Number	Chemical	CAS	Date of publication of report
	Full Assessments		
1	TGIC (Triglycidylisocyanurate)	2451-62-9	April 1994
1a	TGIC Secondary Notification#		
2	Savinase – Proteolytic enzymes in detergents	Various	Feb 1993
3	Glutaraldehyde	111-30-8	June 1994
4	HCFC-123	306-83-2	March 1996
4a	HCFC-123 Secondary Notification#		
5	Sodium ethyl xanthate	140-90-9	May 1995
5a	Sodium ethyl xanthate Secondary Notification#		
6	2-butoxyethanol in cleaning products	111-76-2	Oct 1996
7	1,4-dioxane	123-91-1	June 1998
8	Trichloroethylene	79-01-6	March 2000
9	Chrysotile asbestos	12001-29-5	Feb 1999
11	N-vinyl-2-pyrrolidone	88-12-0	April 2000
13	<i>Para</i> -dichlorobenzene	106-46-7	Dec 2000
14	<i>ortho</i> -dichlorobenzene	95-50-1	Feb 2001
18	Ammonium, potassium and sodium persulphate in hairdressing	7727-54-0; 7727-21-1; 7775-27-1	June 2001
21	Benzene	71-43-2	Sept 2001
22	Limonene*	5989-27-5; 5989-54-8; 138-86-3	May 2002
23	Acrylamide	79-06-1	May 2002
NA/405S	Polymer in Reactint Red X64 Secondary Notification#	Not assigned	April 2003
24	Methylcyclopentadienyl manganese tricarbonyl (MMT)	12108-13-3	June 2003
25	Alkyl phosphate anti-valve seat recession additive	Exempt information	July 2003
NA/418S	Z-28 Secondary Notification#	Not assigned	Dec 2003
26	Sodium alkylbenzene sulfonate anti-valve seat recession additive	78330-12-8	Feb 2004
27	Tris(2,3-dibromopropyl) phosphate	126-72-7	Nov 2005

PEC Assessment Number	Chemical	CAS	Date of publication of report
NA/752S	Polymer in E7581 Secondary Notification#	Not assigned	Nov 2005
Preliminary Assessments			
10	Acrylonitrile	107-13-1	Feb 2000
12	Glycolic acid in cosmetics	79-14-1	April 2000
15	Tetrachloroethylene	127-18-4	June 2001
16	Short chain chlorinated paraffins	Various	June 2001
17	Trisphosphates	Various	June 2001
19	Hydrofluoric acid	7664-39-3	June 2001
20	Polybrominated flame retardants	Various	June 2001

\* Limonene exists as its isomers, d-limonene (CAS Number 5989-27-5), l-limonene (CAS Number 5989-54-8), and dl-limonene (CAS Number 138-86-3; which replaces the former CAS number 7705-14-8)

# Under the Act, a secondary notification of a chemical that has been assessed as a PEC or as a new chemical which has since been listed on AICS may be required where an introducer of the chemical becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Six secondary notification assessments have been conducted to date.

Note: Octabromobiphenyl (CAS No. 27858-07-7) and decabromobiphenyl (CAS No. 13654-09-6) were declared priority existing chemicals (PECs) for full assessment on 6 July 2004. Since applications for assessment were not received, the two chemicals were removed from the AICS as per section 63 of the *Industrial Chemicals (Notification and Assessment) Act 1989*. The chemicals were not subjected to an assessment.

## B. Other chemical information products

Chemical(s)	Content of assessment	Sources utilised	Reason for assessment
<i>Other assessments</i>			
Tetrachlorobenzyl toluenes; polychlorinated naphthalenes; polychlorinated diphenyl ethers; polychlorinated styrenes	Identification of quantities imported and manufactured, uses, amounts produced and/or released as by-products of processing and manufacture, and recommendations with regard to the need or not for further assessment.	International assessments; literature searches; data from Australian industry, NGOs, unions, government agencies, specialist overseas agencies	Potential to persist and bioaccumulate in the environment,
Potassium perfluorobutane sulfonate	Identification of quantities imported and manufactured, hazard assessment and classification, and recommendations.	Published and unpublished studies.	Potential hazard of this chemical.
Short Chain Chlorinated Paraffins (SCCPs)	Environmental exposure assessment.	International assessments; literature searches; data from Australian industry, NGOs, unions, government agencies, specialist overseas agencies	A follow up report to the SCCPs Priority Existing Chemical Assessment Report No. 16.

Chemical(s)	Content of assessment	Sources utilised	Reason for assessment
Glyceryl monothioglycolate; Cobalt(II) chloride hexahydrate; Diazolidinyl urea; Dowicil 200; Imidazolidinyl urea; Cl+Me-isothiazolinone; 2-Nitro-4-phenylenediamine; Abietic acid; N-Cyclohexyl-2-benzothiazolesulfenamide; Zinc dimethyldithiocarbamate; Wool alcohols; Coconut diethanolamide; Basic Red 46; Benzalkonium chloride; Phenol formaldehyde resin; Toluenesulfonamide formaldehyde resin; 4-tert-Butylphenol formaldehyde resin; Sodium metabisulfite; Triethyleneglycol dimethacrylate	Classification of these chemicals against the Approved Criteria for sensitisation.	Literature searches and specialist overseas agencies.	Known potential for skin sensitisation.
<i>Information sheets</i>			
Sodium laurel sulphate; ammonium laurel sulphate	Toxicity overview, information on import, manufacture and use, regulatory status; information on use in products	International assessments; literature search; examination of secondary sources; Australian regulatory publications	High level of enquiries to NICNAS stimulated by media reports of adverse effects.
Copper; sodium hydroxide; sulfuric acid; urea; chloroethene; methylene chloride	Identity, properties, import, manufacture and use, regulatory status, toxicity and health and safety information	International assessments; Australian regulatory publications	Present in high volume in Australia, have not undergone a hazard assessment by NICNAS
Ortho-phthalaldehyde; calcium hemihydrate	Toxicity overview, information on import, manufacture and uses in Australia, regulatory status, reasons for non-selection as candidate chemicals	Literature searches, OECD databases; Australian regulatory publications	Nominated as PECs but not selected
Short chain chlorinated paraffins	Recommendations of the environmental exposure assessment of SCCPs	NICNAS Environmental exposure assessment of SCCPs	Based on assessment findings of high aquatic toxicity and persistence.
Perfluorooctane sulfonate (PFOS)	Guide for disposal options for PFOS waste	Advice received from the States and Territories	High level of enquiries about waste disposal options for PFOS

Chemical(s)	Content of assessment	Sources utilised	Reason for assessment
Polybrominated flame retardants (PBFRs)	Current Australian use and regulatory activities on PBFRs.	Preliminary PEC on PBFRs; data from Australian industry, NGOs, unions, government agencies, specialist overseas agencies.	High level of public and media interest.

## ATTACHMENT 2.2 – PEC REPORT RECOMMENDATION TYPES

### *Recommendations directed to peak bodies*

- exposure standards
- hazard classification
- poisons scheduling
- dangerous goods classification
- establishment of biological monitoring guidelines and a biological exposure index
- establishment of formal health surveillance guidelines
- the phase-out of a chemical (chrysotile asbestos)
- better coding of injury statistics

### *Recommendations directed to state/territory government authorities*

- compliance action to improve industry performance and ensure compliance with standards and codes of practice
- preparation and dissemination of plain English information sheets

### *Recommendations directed to industry*

- workplace control measures to reduce workplace exposure such as -
  - the use of certain engineering controls and/or personal protective equipment
  - phasing out of certain uses of a chemical (eg. trichloroethylene in aerosols and in cold cleaning)
- improved hazard communication through -
  - update and review of labelling
  - update and review of information contained in material safety data sheets
- implementation of training and education
- routine air monitoring
- establishment or updating of industry codes of practice
- safer product formulation
- safer packaging
- establishment of health surveillance program
- safe disposal of waste
- development of emergency plan
- the filling of data gaps about a chemical or safer alternatives to the chemical through further research such as toxicity testing

Occasionally recommendations are made to other organisations. For instance, the PEC assessment of limonene included a recommendation to the Australasian College of Dermatologists that medical practitioners should include oxidised limonene in patch testing of hand eczema patients.

## APPENDIX 3: REPORT OF BRAINSTORMING WORKSHOP – CONDUCTED AUGUST 2003

Summary of the Brainstorming Workshop of issues for consideration in the review of the Existing Chemicals Program (the Program) held at the National Industrial Chemicals Notification and Assessment Scheme, Marrickville, on Friday the 8<sup>th</sup> August 2003, from 10.30 am – 4 pm.

### Participants

Geraldine Andrews	New South Wales Environmental Protection Agency
Graeme Barden	Australian Government Department of Environment and Heritage
David Collins	Australian Institute Occupational Hygienists
Kersi Contractor	Coates Australia Pty Ltd
Graeme Croft	Coates Australia Pty Ltd
Tom Fisher	National Occupational Health and Safety Commission
Stephen Holland	Plastics And Chemicals Industries Association
Neale Jackson	Faculty of Applied Science, Royal Melbourne Institute of Technology
Margaret Hartley	National Industrial Notification and Assessment Scheme
Jeff Langley	Worksafe Western Australia
Mariann Lloyd-Smith	National Toxics Network
Geoff MacAlpine	Australian Consumer & Specialty Products Association
Dusanka Sabic	National Industrial Notification and Assessment Scheme
Sneha Satya	National Industrial Notification and Assessment Scheme
Paul Verren	Asia Pacific Specialty Chemicals Ltd
Robert Ward	DuPont (Australia) Ltd
Jane Weder	National Industrial Notification and Assessment Scheme
John Wickens	National Toxics Network
Debbie Willcocks	National Industrial Notification and Assessment Scheme

### In attendance (representing NICNAS - National Industrial Notification and Assessment Scheme)

Graham Harvey	Paul Harvey	Roshini Jayewardene
Trang Pham	Jun Zhang	Stephen Zaluzny

### Apologies

Bronwyn Capanna (Australian Consumer & Specialty Products Association), Sue Connor (Greenpeace Australia Pacific), Efan Koch (Ciba Specialty Chemicals Pty Ltd), Sue Pennicuik (Australian Council of Trade Unions).

### Presentations

The Brainstorming Workshop commenced with four power point presentations by NICNAS staff. The presentations included a welcome, introduction and 'setting of the scene' by the Director (Margaret Hartley) and overview of the review process (Dusanka Sabic). Presentations on the current Existing Chemicals Program (Sneha Satya), International Existing Chemicals Programs (Debbie Willcocks), and Issues identified to date (Jane Weder) were also presented.

The presentations were based on three Background Papers ('*Current Program*', '*International Programs*', '*Issues Identified to Date*'), which had been circulated to participants prior to the workshop. The Director (NICNAS) identified the following challenges for the review:

- What will an Existing Chemicals Program look like in 2010?
- Where does chemical safety need to be?
- What are the models for the future?

## Workshop format

Participants agreed on a 'round table' format for the Workshop. The issues discussed were based on those raised during a number of focus consultations which had been undertaken by Program staff (June-July 2003) with ~ 20 individuals/groups familiar with the Program and or chemical safety issues. The Workshop issues fell into the following categories:

- Role of the Program
- Operation of the Industrial Chemicals Notification and Assessment (ICNA) Act
- Relationship with other agencies
- Program priorities & processes
- Priority Existing Chemical (PEC) assessments
- Communication & access to information, and
- Other issues.

## Introductory remarks

Following the presentations, participants raised a number of initial comments. In relation to why the review of the Program was being undertaken, the Director (NICNAS) noted that a planned review of the Program had been delayed for two years because of a major re-setting of the European existing chemicals assessment program.

International collaboration, co-ordination with international programs, and seeking an 'Australian purpose and relevance' were suggested as ways forward for the Program.

A view was put that while the Program's technical information was of a high quality, the Program's message is not getting out.

The need to analyse the uptake of Program recommendations, communicate with downstream users, collect use data, and focus on industry sectors were raised. The removal of the NICNAS threshold for company registration was suggested as a means of engaging all chemical traders in the management of chemical safety in Australia. A 'NICNAS Number' for all chemical traders was suggested.

The use of international hazard assessments as a basis for national risk assessments was discussed. A point was made that while appropriate hazard assessment may be relevant across the world, a risk assessment may vary from country to country because exposures to and / or uses of the chemical may vary from country to country.

Information from the European REACH (Registration, Evaluation, and Authorisation of Chemicals) Program and the United States High Production (HPV) Challenge Program were seen as providing in due course a large amount of information in Australia on the hazards of chemicals.

Linking relevant international assessment reports and information to the Australian Inventory of Chemical Substances (AICS) was suggested as a way of increasing access to more information about chemicals listed on the AICS. This was noted as pertinent since the AICS was scheduled for listing on the NICNAS web site. (NICNAS stated that a training program with industry stakeholders about the features of the electronic AICS was planned). Linking the AICS to trade names and reducing the size of the AICS, eg. removing obsolete chemicals, was also raised (and discussed later).

Concern was expressed that chemicals should not be dumped in developing countries and developing countries are concerned that if there is no sponsor country to take a chemical forward (for assessment), then no information about that chemical may become available.

The example of ChemCollect data (a scheme whereby primary producers may bring unwanted agricultural and veterinary chemicals to nominated places) was suggested as a way of getting a handle on chemicals that are used.

## Workshop issues

A synopsis of the comments and points made during the workshop that followed are given below.

**Role of the EC Program:** The objectives of the *Industrial Chemicals (Notification and Assessment) Act* (the Act) were raised and discussed in terms of whether or not the Program's policy objectives were adequately met by the current Act. The following issues were raised:

- Does the assessment of Priority Existing Chemicals (PECs) per se sufficiently meet the objectives of the Act?
- Is legislative change 'on the table'?
- How does one best address the role of the Program?

- How would one address a chemical reduction/replacement strategy? (Is this best driven by consumer demand and access to information?)
- Should a focus be on sensitive populations (such as children) and cradle-to-the-grave assessments?

The following points were also made:

- compliance activities should reside with NICNAS
- map the role of the Program against the objectives of the Act
- develop a communication strategy
- ensure Program processes and activities are transparent
- place an emphasis on decreasing the use of hazardous chemicals (based on information, risk assessment and cost-benefit analysis)
- be proactive rather than reactive, eg. set up a forum such as a community advisory committee to oversee this activity. Consider a model such as the Scheduled Waste Management Group and the National Advisory Body on Scheduled Wastes
- monitor chemicals in the environment to assist in identifying priorities
- develop more effective links with State & Territory organisations
- set up an 'inventory of use'; allow the tracking of chemical use via NICNAS, and
- ensure access to independent advice across all sectors - not just toxicological advice.

**Operation of the Act:** The role of compliance and other government bodies in achieving objectives of the Act were discussed. A point was made that the current chemical safety framework in Australia is a 'tangled web'. The following issues were raised:

- Is compliance a focus for the Program?
- Are not all stakeholders compliance officers?
- Where do the NICNAS and NOHSC legislative boundaries start and stop? Is this clearly defined for stakeholders?
- What is the purpose of NICNAS information if there is no follow-up?
- Should there be additional legislative power for NICNAS.

The following points were also made:

- make 'in-field' compliance part of the Program (consider the costs)
- engage industry in compliance activities
- extend the scope of the Act to engage small to medium as well as large enterprises, eg. NICNAS number
- NICNAS to have carriage for compliance of its recommendations (consider the resource implications)
- map the chemical safety framework in Australia to identify work and barriers
- enable the banning / restriction of chemicals
- a holistic approach to chemicals (beyond NICNAS) and an 'overall oversight' of chemicals is required in Australia
- a structural review of other state / national chemical regulators is required (what is the model?), and
- NICNAS to provide a leadership role.

**Relationship with other agencies:** The importance of developing intrinsic relationships with not just other government agencies but also industry, professional organisations and end-users was raised. A point was made that States and Territories are better placed than NICNAS to enforce recommendations because specific legal obligations rest in State and Territory legislation.

Access to information such as 'who was using what and where' was raised as a way of assisting States and Territories in this task. The need to build relationships beyond industry group membership was raised. The following issues were raised:

- why have risk assessment without a mandatory risk management system?
- develop relationships with end-users via States and Territories and industry
- register all chemical traders

- hazard threshold for activity, eg. states and territories prioritise most hazardous chemicals such as carcinogens, mutagens and reproductive toxins
- build on relationships with small to medium enterprises, including local government authorities
- ensure recommendations are legally enforceable;
- make more information accessible and understandable - link chemicals to products
- facilitate consistent national risk management, and
- raise the profile of NICNAS.

**Program priorities & processes:** A point was raised that it is not the number of assessments undertaken but rather quality and follow through to the end users which is important. A point was expressed that 'how best to fit the information at the local level' was the issue and that more targeted reviews on a variety of issues (rather than doing less assessments) were ways forward. Questions were raised about the value of reducing the number of chemicals listed on the AICS (by removing chemicals not in use), eg. purpose, value for money. The following issues were raised for consideration during the review:

- Why review more chemicals if few recommendations are taken up
- How many recommendations are taken up?
- How best to manage chemical information for maximum benefit?
- Is there a value in reducing the number of chemicals listed on the Australian Inventory Chemicals Substances (AICS)? Is this an important outcome? What happens if chemicals removed from the inventory are found to have a use in the future? Have these chemicals been assessed or grandfathered? Less chemicals to manage (need to define)?

The following points were also made:

- focus on priority chemicals, ie. chemicals of national interest
- improve the uptake of recommendations
- more targeted assessments on focussed issues and life cycle analysis
- be outcome focused
- draw on overseas data and focus on Australian issues
- focus on real priorities utilising a range of assessments as required, eg. partial to full assessments
- focus on collecting use and exposure information
- there is public concern regarding the AICS – not enough information about all these chemicals
- focus on hazardous chemicals and not non-hazardous chemicals
- place limits on the percentage of a chemical in a product
- to prioritise, use occupational health and safety information, focus on chemicals of concern, focus on implementation of recommendations, and
- work with industry on the uptake of recommendations.

**Priority existing chemical (PEC) assessments:** Purposes of the PEC assessment reports were discussed. It was noted that it was important that the PEC assessment reports be useful –having relevance, eg. as a compliance and training guide (NOHSC, States and Territories, Industry Codes of Practice). What is the public use? It was noted that the reports were very large and the recommendations appear 'lost' in the detail. With regard to communicating the report recommendations, a point was made that it was important to analyse where any breakdowns were taking place. A point was made that each PEC was different and a 'strategy per chemical' was required.

Because the preparation of a PEC assessment report is lengthy, it was suggested that information about where the assessment was up to should be publicly available. The following issues were raised:

- What is the purpose of the PEC assessment reports?
- Is the information communicated in the right form?
- Will compliance activities improve the uptake of PEC report recommendations?
- How can information in Material Safety Data Sheets best be improved?
- How best to access information on subtle/chronic effects of a chemical?

The following points were also made:

- the reports should also be for the public
- better highlight recommendations at the front of the reports
- engage stakeholders when formulating recommendations; be proactive, eg. trial basis with companies
- make sure recommendations can be acted upon in language understandable – place the recommendations in the front of the reports and in Program products, eg. compliance guide
- train people in the use of priority existing chemicals ie. strategy for the chemical
- ensure mandatory uptake of Material Safety Data Sheet and label recommendations
- use an adverse reporting mechanism to assist in prioritising chemicals for assessment
- keep stakeholders informed on the process, eg. consultation
- develop a mechanism for confidential reporting of industry practices/monitoring, and
- follow up recommendation uptake.

**Communication & access to information:** A number of comments were made about communication priorities and strategies for the Program – in particular communication with end-users. A point was made that communication goes beyond the completion of assessments. Another point was made that the (legal) responsibility for communicating chemical safety issues with end-users rests with organisations other than NICNAS. A comment was made that the NICNAS web site was not clear and did not contain product-specific information (which would be useful to the community) nor information on how to report adverse reactions. A point was made that while web linking to relevant overseas reports and information is possible, it was important to 'value-add' for the Australian public. The following issues were also raised:

- Is communication a partnership with industry?
- How best to respond to emerging issues?

The following points were also made:

- communication with end-users is important (how best to achieve?)
- communication goes beyond the completion of the PEC assessment report
- the New Zealand scheme communicates well, eg. regular electronic alerts on web site changes
- information alerts work well
- product specific rather than chemical specific information needed for the community
- adverse reactions reporting scheme for the community
- list chemicals on the web site with hotlinks to information - web site is confusing
- need a central government chemicals information site with links to NICNAS etc
- do industry profiles / do 'cradle to the grave' analysis
- include responses to requests to variations on assessment reports in the final reports, and
- consumers are seeking guidance.

*Other issues:* Participants raised a number of other issues. Points were made that the AICS was seen as a 'missing link' and chemical names could be very confusing. A question was asked if it was possible to work with industry organisations, eg. cosmetic companies, to assist consumers in identifying synonyms for ingredients listed on products. The following issues were also raised:

- assess products
- label all ingredients, eg. not just cosmetics
- develop a communication program with industry bodies
- better analysis of mortality, morbidity, cancer incidence and adverse incidence data; source 'industry-based adverse incident reporting data', and
- raise issues which may not be applicable to the Program with appropriate organisations.

The workshop closed at 4.00 pm. At the conclusion of the workshop, copies of the NICNAS power point presentations were made available to participants. As a next step, participants were encouraged to forward to J Weder (NICNAS) completed copies of the paper '*Issues Identified to Date*' (The paper seeks comments from participants on further issues and priorities for consideration during the review). Copies of the summary of the workshop are to be forwarded to participants.

## APPENDIX 4: COMMITTEE AND WORKGROUP TERMS OF REFERENCE AND MEMBERSHIP

### REVIEW STEERING COMMITTEE – Terms of Reference (original)

#### Introduction

NICNAS is undertaking a review of the Existing Chemicals Program (the EC Program).

The current Program, which has been in operation for five years, was scheduled for review two years ago. International changes to existing chemicals assessment programs mooted in Europe and elsewhere, however, delayed the review. Due to recent decisions regarding these international programs, it is now considered timely to undertake the Program review.

The aim is to review the current Program with a view to its:

- efficiency and effectiveness
- flexibility and responsiveness to stakeholder needs, and
- harmonisation with comparable schemes and reflecting international trends.

The review will be looking at how to determine national priorities for assessment of existing chemicals, better utilise overseas testing and assessment program outputs, and address the needs of the community and industry regarding access to sound information on chemicals hazards and risks.

The Steering Committee is an expert group, which has been established to assist the NICNAS office. The Steering Committee will set a framework for the review and oversee its activities. The Steering Committee will be able to seek additional expert advice, for example from individuals, technical working groups or consultants as needed. The Steering Committee will report to the Director, NICNAS.

The review will be completed when the final report on the Program is published. This is expected to occur by February 2006.

#### Membership

The Steering Committee shall consist of 10 members, including an independent chair who will be Dr Wafa El-Adhami from the Office of the Chemical Safety (OCS, Canberra). Membership will therefore comprise of:

- independent chair
- three community representatives
- three industry representatives, and
- three government representatives.

with the Director (NICNAS) as an Ex-Officio (Non-Voting) member of the committee.

The community and industry representatives will be appointed via NICNAS's Community Engagement Forum and Industry Government Consultative Committee, respectively.

The government representatives shall consist of a nominee from the Australian Government Department of Environment and Heritage, NICNAS, and the NICNAS/States and Territories Memorandum of Understanding (MOU) Group.

Members shall be appointed on:

- the basis of either their knowledge of industrial chemicals in a regulatory context, and/or
- ability to provide expert advice, and/or
- an understanding of community concerns related to the regulation of chemicals, and/or;
- knowledge of Government processes involving industrial chemicals regulation.

At its initial meeting, the Steering Committee will: agree on the Terms of Reference; establish the framework and timeline for the review and recommend activities pertaining to the preparation of the public Discussion Paper and final report on the Program.

It is expected that the Steering Committee will meet two or three times in the next 6 months, with additional work out of session during that time. The meetings will be conducted either face-to-face or through teleconferencing. The Steering Committee will adopt NICNAS's framework for Community Engagement. A quorum will constitute the Chair or nominee, two industry representatives, two community representatives and two government representatives.

### Terms of reference

The Steering Committee will review the current Program with a view to its:

- efficiency and effectiveness
- flexibility and responsiveness to stakeholder needs, and
- harmonisation with comparable schemes and reflecting international trends.

The Steering Committee, therefore, will:

1. Oversee the review processes and provide advice on issues relevant to the Program review
2. Contribute to and provide strategic direction on the:
  - development of the public options paper
  - consultation strategies
  - review of submissions received, and
  - final paper on the future direction of the Program
3. Assist with other tasks relevant to the review at the request of the Director (NICNAS)
4. Draft Final Report and Recommendations on the future of the Existing Chemicals Program to the Director, NICNAS by February 2006.

## REVIEW STEERING COMMITTEE – Membership

Mr Tom Fisher (Chair)  
Senior Executive Manager, OASCC

Dr Wafa El-Adhami (Chair)  
Deputy Director, Office of Chemical Safety

Ms Jane Bremmer  
Coordinator, Alliance for a Clean Environment

Representing community environmental interests

Mr Bob Graf  
Team Leader Reform, NICNAS

Representing NICNAS

Mr Stephen Holland  
Director, Corporate and Community Relations  
Plastics and Chemicals Industries Association

Representing industry

Ms Sylvia Kidziak  
Principal Consultant, Occupational Health, Safety &  
Environment Policy, Australian Business Ltd

Representing industry

Dr Jeff Langley  
Principal Scientific Officer/Inspector (Occupational  
Hygiene), Department of Consumer and Employment  
Protection WA

Representing states and territories

Mr Geoff MacAlpine  
Director, Science and Policy, ACCORD Australasia

Representing industry

Ms Renata Musolino OHS Information Officer, Victorian Trades Hall Council	Representing worker health and safety
Mr Graeme Barden (then Mr Greg Plummer) Director, Chemical Assessment Section, Department of the Environment and Heritage (DEH)	Representing DEH
A/Professor Chris Winder School of Safety Science, University Of NSW	Representing community public health interests
<i>Ex-officio member (non-voting)</i>	
Dr Margaret Hartley Director, NICNAS	
Secretariat	
Mr Stephen Zaluzny, Scientific Officer	
Dr Venky Krishnamurthy, Scientific Officer	

## **TECHNICAL WORKING GROUPS – Membership**

### **Working Group 1 members**

Mr Tom Fisher (Chair) Senior Executive Manager, OASCC	
Mr Bob Graf (Chair) Team Leader Reform, NICNAS	
Ms Susie Birdsall Environmental, Health and Safety Manager, Bayer Australia New Zealand	Representing industry
Mr Philip Hine Manager, Environmental Regulation, Department of Environmental Protection WA	Representing states and territories
Mr Geoff MacAlpine Director, Science and Policy, ACCORD Australasia	Representing industry
Dr Sneha Satya Team Leader, Review and Treaties, NICNAS	Representing NICNAS
Dr Bro Sheffield-Brotherton Chairman, Sustainable Solutions Pty Ltd	Representing community
A/Professor Chris Winder School of Safety Science, University Of NSW	Representing community
Secretariat	
Mr Stephen Zaluzny, NICNAS	

### **Working Group 2 members**

Mr Bob Graf (Chair) Team Leader Reform, NICNAS
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Mr Greg Balka Manager, Chemical and Plant Standards, WorkSafe Victoria	Representing states and territories
Dr Graham Harvey Senior Scientific Officer, Rapid Risk Assessment, NICNAS	Representing NICNAS
Dr Mariann Lloyd-Smith Senior Advisor, National Toxics Network	Representing community
Mr Geoff McAlpine Director, Science and Policy, ACCORD Australasia	Representing industry
Dr Bro Sheffield-Brotherton Chairman, Sustainable Solutions Pty Ltd	Representing community
Mr Robert Ward Senior Technical Specialist, DuPont Australia Ltd	Representing industry
Secretariat Mr Stephen Zaluzny, NICNAS	

### **Working Group 3 members**

Mr Bob Graf (Chair) Team Leader Reform, NICNAS	
Mr Jud Agius NSW Department of Environment and Conservation	Representing states and territories
Mr Stephen Holland Director, Corporate and Community Relations, Plastics and Chemicals Industries Association	Representing industry
Dr John Issa Principal Consultant, Cintox Pty Ltd	Representing industry
Dr Bro Sheffield-Brotherton Chairman, Sustainable Solutions Pty Ltd	Representing community
Ms Debbie Willcocks Team Leader Rapid Risk Assessment, NICNAS	Representing NICNAS
A/Professor Chris Winder School of Safety Science, University Of NSW	Representing public health
Secretariat Mr Stephen Zaluzny, NICNAS	

## APPENDIX 5: EXECUTIVE SUMMARY AND PROPOSALS AS PRESENTED IN DISCUSSION PAPER FOR PUBLIC COMMENT – APRIL 2006

### EXECUTIVE SUMMARY – PROPOSALS FOR CHANGE

#### A NEW MODEL FOR THE EXISTING CHEMICALS ASSESSMENT PROGRAM

Australians use industrial chemicals every day, eg. in cleaning products, cosmetics and paints. To aid in the safe and sustainable use of chemicals in our daily lives, it is important to assess the health and environmental effects and risks posed by chemicals and make recommendations – and adequate information – widely available.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulates the introduction of new industrial chemicals and assesses the potential occupational health and safety (OHS), public health and environmental risks associated with their introduction or use.

NICNAS also assesses those chemicals that are already in use in Australia (known as existing chemicals) on a priority basis in response to specific concerns about their potential health and/or environmental effects. The Existing Chemicals Assessment Program is currently under review and a new model is proposed. It is proposed that key elements of the existing framework be retained, that other elements are modified and that new elements are added to enhance the program.

The proposed model seeks to improve the three basic elements of the program:

- inputs required for an effective program
- processes required for efficient delivery, and
- outputs necessary to address stakeholder needs.

#### Inputs

The new model seeks to improve the quality of inputs to increase the effectiveness of the program to ensure that both the right and appropriate chemicals are identified for assessment.

#### Proposal 1

To ensure that the concerns of stakeholders are captured by NICNAS, improve communications by:

- developing and publishing a layperson's guide to the Existing Chemicals Assessment Program
- improving the NICNAS website, particularly for the community
- conducting seminars and education programs
- publishing a 'Who's who and what do they do?' guide for the various government agencies, eg. on the website
- developing and publishing an information flow diagram for existing chemicals
- enhancing the response to enquiries, including development and publication of a procedure for their analysis
- producing a bulletin on the progress of existing chemical assessments and issues
- publishing more topical information from international sources on the website

#### Capturing the concerns of stakeholders

While NICNAS communication mechanisms are generally regarded as sound, greater sensitivity to stakeholder concerns is required. This can be achieved through enhancement of the channels of communication to NICNAS and removal of communication barriers.

More frequent calls for nomination of chemicals for assessment are more likely to capture topical issues and concerns.

#### Proposal 2

Increase the frequency of calls for public nominations of chemicals for assessment to, eg. every two years.

### Screening of AICS-listed chemicals in use

It is proposed that industrial chemicals in use in Australia, listed on the Australian Inventory of Chemical Substances (AICS), be screened. To efficiently screen the large number of chemicals on AICS, information from current international assessment activities and the results of other national screening programs will be utilised.

#### Proposal 3

Screen AICS-listed chemicals for possible assessment, with priority given to non-assessed chemicals on:

1. the NICNAS High Volume Industrial Chemicals List (HVICL), which NICNAS compiles on a regular basis, and
2. the Hazardous Substances Information System (HSIS), which is the list of hazardous substances compiled by the ASCC (Office of the Australian Safety and Compensation Council).

#### Proposal 4

For the remaining chemicals, give priority in screening to those in use with:

- carcinogenicity, mutagenicity, reproductive toxicity (CMR) hazards, and/or
- persistence, bioaccumulation and toxicity (PBT) characteristics.

#### Proposal 5

To develop criteria for the AICS screening process, taking into account factors such as volume, use, hazard and exposure potential. This will be done in consultation with stakeholders, and with the development and use of 'tools' such as structure-activity relationship modeling.

### Surveillance, monitoring and post-market reporting for industrial chemicals

It is proposed to examine and introduce a nationally coordinated system of surveillance, monitoring and post-market reporting for industrial chemicals. The first step will be to scope the nature, source and quality of surveillance, monitoring and post-market data already collected prior to the introduction of any national reporting scheme. The second step will be to refine the system with a view to developing a best practice mechanism.

#### Proposal 6

Examine and introduce a nationally coordinated system of surveillance, monitoring and post-market reporting for industrial chemicals which would:

- increase the knowledge base on industrial chemicals in use in Australia and therefore lead to safe and sustainable use
- provide information to assist with risk management strategies through identification of adverse impacts
- provide early warning of emerging patterns of health and environmental risks, and
- provide assistance in development of best practice surveillance, monitoring and post-market reporting activities via a feedback mechanism.

### Processes

Consistent with the aims of enhanced efficiency and effectiveness, it is proposed that NICNAS develop its administrative processes to be more transparent and enhance the response to concerns from stakeholders.

#### Filtering of inputs

Transparent administrative processes will be developed and/or modified to filter out non-NICNAS matters (for referral to the appropriate agency) and determine the level of response required to address the concerns of stakeholders. For example, an assessment may be required or a quick email response may suffice.

#### Proposal 7

Develop and modify NICNAS administrative processes to filter out and redirect non-NICNAS matters and determine the level of response and/or assessment required. Publish the filtering process to enhance transparency in the decision-making processes.

## Screening and selection of chemicals

Once it is determined that some level of assessment is required, screening of the chemical using scientifically based criteria is proposed to identify priorities for assessment.

### Proposal 8

In consultation with stakeholders, develop scientifically based criteria for the screening of chemicals for identification and prioritisation for assessment.

Publish the screening process and screening decisions on the NICNAS website to aid in enhancing the transparency of the decision-making processes.

Selection criteria and procedures are used for the screening and selection of chemicals nominated for assessment as Priority Existing Chemicals (PECs). Enhanced processes for these criteria are also proposed.

### Proposal 9

Establish a technical working party to revise the PEC selection criteria and procedures. The revised criteria would be published on the NICNAS website and subject to further public comment and stakeholder engagement according to an agreed timetable.

## Enhanced information-gathering processes

Currently the data collection powers of the legislation are limited to declared PECs and chemicals being considered for declaration as PECs. Collection of information for other types of assessment or information product is not currently supported by legislation.

### Proposal 10

Amend the legislation to broaden the information-gathering powers of NICNAS for all types of assessments and related processes.

An important group of stakeholders in the regulation of existing chemicals are the downstream users, who include formulators and suppliers of industrial chemicals and chemical products.

### Proposal 11

Engage downstream users on a chemical-specific basis, ie. identify relevant downstream users at the beginning of each chemical assessment.

## Simplified secondary notification

The current process for the re-assessment of existing chemicals originally assessed as new chemicals is unnecessarily lengthy.

### Proposal 12

Streamline the secondary notification process for existing chemicals originally assessed as new chemicals:

- using the new chemicals assessment process with its shorter timeframes, or
- using the proposed new model with its filtering and screening processes and range of assessment types for prioritisation for assessment

## Engagement and awareness

The review has highlighted the need to:

- improve the relationship between NICNAS and other government agencies, and
- make more use of overseas assessments.

### Proposal 13

Broaden the NICNAS MOU arrangement with states and territories to improve the relationship with agencies not directly represented on the MOU committee, and

Clarify the roles of NICNAS and the state and territory agencies, eg. publish a 'Who's who and what do they do?' guide on the website.

**Proposal 14**

Clarify the roles of the various Federal agencies and existing networks, and establish the appropriate forums to ensure proper regulation of industrial chemicals at the national level.

**Proposal 15**

Provide more international information to stakeholders to enhance awareness of current chemical issues, with a view to enhancing the flow of information to NICNAS.

**Proposal 16**

Develop bilateral arrangements for existing chemicals with other major trading countries.

**Outputs****New types of assessment options**

In order to enhance the flexibility and responsiveness of the Scheme, it is proposed to increase the number and variety of options available to NICNAS to better respond to the concerns of stakeholders. To provide more information on more chemicals, a more targeted approach is proposed.

**Proposal 17**

Develop three levels of assessment or 'product', namely:

- a product for information only
- an advisory assessment, containing advice or guidance – proposed when advice or guidance is to be included with the information, and
- assessment reports of various types – likely to contain advice and which may contain recommendations of a regulatory nature.

**Enhanced controls**

To aid in the protection of the Australian people and the environment, it is proposed to increase NICNAS's legislative powers to ban, phase-out or severely restrict the use of certain high hazard/high risk industrial chemicals.

**Proposal 18**

Increase NICNAS's legislative powers to ban certain high hazard/high risk industrial chemicals to aid in the protection of the Australian people and the environment.

**Proposal 19**

Legislate to increase NICNAS's powers to control the use of industrial chemicals through measures such as:

- restriction of use of the chemical to certain industries and/or restriction of use to certain trained persons
- authorisation process to allow introduction of high hazard or high risk chemicals for certain purposes, eg. research
- licensing powers for chemicals
- chemical control orders or permits to control the use, handling or disposal of a chemical
- use of NICNAS Registration number as a reporting and tracking tool
- powers to recall supply and sale of chemicals and powers to prosecute illegal supply and sale
- powers to regulate articles with potential to release high risk chemicals (NICNAS currently can regulate chemicals released from articles but not articles themselves)

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- tools to enhance improved surveillance reporting, and/or infringement notices, naming and shaming and community orders.
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#### **Improved uptake of recommendations**

The implementation of recommendations in NICNAS assessment reports has improved. However, further improvements are required.

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#### **Proposal 20**

Improve the uptake of NICNAS recommendations by:

- phrasing the recommendations in assessment reports in a manner which makes the required actions more relevant, feasible and obvious to the relevant stakeholders, ie. clear 'action' statements
  - enhancing consultation with stakeholders during the assessment process and before recommendations are finalised to ensure recommendations can be implemented, and
  - regularly measuring the uptake of recommendations to determine whether expected outcomes are being realised, ie. enhancement of NICNAS's performance results for implementation of recommendations.
-

## APPENDIX 6: SUMMARY OF PUBLIC FORUMS – MAY & JUNE 2006

### DATES OF EXISTING CHEMICALS PROGRAM REVIEW PUBLIC FORUMS MAY-JUNE 2006

15 May	Sydney	10 am and 7 pm
16 May	Perth	2 pm and 7 pm
17 May	Broome	7 pm
18 May		9 am
22 May	Adelaide	2 pm and 7 pm
23 May	Darwin	2 pm and 7 pm
29 May	Townsville	2 pm and 7 pm
29 May	Canberra	2 pm and 7 pm
30 May	Brisbane	2 pm and 7 pm
31 May	Hobart	7 pm
1 June		9 am
1 June	Melbourne	7 pm
2 June		10 am
13 June	Inverell	12 noon

### ATTENDANCE AT PUBLIC FORUMS – BY SECTOR<sup>1</sup>

City	Public (%)	Industry (%)	Government (%)	Other (%)	Total attendance (nos on sign-in sheet)
Sydney <sup>2</sup>	27	30	33	10	38 (24) <sup>2</sup>
Perth	24	35	18	24	25 (17)
Broome	25	0	75	0	5 (4)
Adelaide	22	6	39	33	19 (18)
Darwin	17	0	83	0	6 (6)
Townsville	50	50	0	0	2 (2)
Canberra <sup>2</sup>	20	20	30	30	9 (9) <sup>2</sup>
Brisbane	33	7	40	20	19 (15)
Hobart	25	0	75	0	13 (12)
Melbourne	38	42	12	8	28 (26)
Inverell	100	0	0	0	6 (6)
<b>Total</b>	<b>35</b>	<b>17</b>	<b>37</b>	<b>11</b>	<b>170 (139)</b>

<sup>1</sup> Determined by details provided in public forum 'sign in' sheets

<sup>2</sup> Determined by responses provided in evaluation sheets

## CONSOLIDATED SUMMARY: COMMENTS ON EACH PROPOSAL FROM PUBLIC FORUMS

The comments given about each of the Proposals from the original Discussion Paper, as made at each Forum session, are presented below.

Please note:

1. Proposal numbering is as for the April 2006 discussion paper – see *Appendix 5*.
2. As there were no attendees at the following sessions, they have been deleted from this listing:  
TOWNSVILLE MONDAY 30 MAY 2006 2 PM TO 4 PM  
BRISBANE TUESDAY 30 MAY 2006 7 PM TO 9 PM
3. Only those venues where comments were received on the given proposal are included in this summary.

### PROPOSAL 1

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon *A user needs assessment on existing information / Status in Australia linked to international activity / Which options are the most beneficial?*

7 - 9 pm *State the benefits of the program more clearly / Note the benefits of industrial chemicals to the community / Expand the who's who directory to include the contact details and functions of state agencies / Provide details of the hazards of chemicals at point of sale*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *NICNAS TV shows 30 mins each week on safe chemical use. Infotainment, not dry science Who's who guide is a great idea but there are too many agencies involved in chemicals. Better integration of ADG code and hazardous substances / Seminars for general public, schools etc on safe chemical use. General education on common chemicals / General support for proposal*

7 - 9 pm *Bias because industry can speak louder than individuals / Mechanism for individuals to bring their concerns to NICNAS via local routes / Need a community representative and guarantee of access on committees*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm *How do we get information to non-English speaking chemical users? / Use indigenous media (radio & TV) to reach aboriginal communities / Targeted education eg. school children / Community education extremely important*

9 - 11 am (THURSDAY 18 MAY) *General agreement*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Discussions with human rights and equal opportunity commission, eg. MCS / Website useability*

7 - 9 pm *Awareness of NICNAS's work*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm *Need to know who regulates what & where to go / Community wants to know regulates what / Need to have a report just on chemicals in general so the community understands sector*

7 - 9 pm *Supported*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Not very interesting and intuitive website - needs to be more user-friendly / Information that is authoritative needs to be available immediately for the user / Users of the website tend to require authoritative information on a chemical of concern immediately - the website needs to be designed to do this. / NICNAS's profile needs to be increased, as it not well known*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *Who's who guide will be excellent. Suggestion for whole-of-government involvement. Updating such a guide? / There is confusion about the elements of each scheme and how they link, eg. MSDS, hazardous substances, work cover schemes / General agreement*

7 - 9 pm *A bulletin published regularly by e-mail or on a web site is a very good idea. Bulletin doesn't need to be lengthy / Chemical information potentially has a huge impact on public health so need to get the information out in lay terms.*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *NICNAS publications should be multilingual, ie. in languages other than English / NICNAS needs a layman's guide to industrial chemicals / Need for community education program on the risks of chemicals, especially for consumers, eg. explaining why twice as much doesn't really mean twice as good. / The name NICNAS was the topic of some discussion and it was suggested that the time had*

come for the name to be changed / NICNAS needs to include local councils in its communication strategy, eg. make a bulletin available. The council officer is often the first point of contact for the public / NICNAS should really increase the amount of training it conducts, especially for end-users. / The improved labelling of domestic products/chemicals need to be developed into a specific proposal. / Better labelling of fragrances is required and is really a right to know issue. / The existence of NICNAS as an organisation needs to be promoted more. / Overall there was general support of the proposal.

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm NICNAS should target specific occupations in its training and seminars. An example given was the drycleaner and the use of trichloroethylene.

9 - 11 am (THURSDAY 1 JUNE) NICNAS was better known when it was associated with NOHSC and that now is not well known. / The question of why there are four bodies/organisations looking at chemicals was raised. It was especially of concern as many chemicals have several uses and therefore more than one regulator may have assessed the same chemical. / Proposal supported.

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm Work with the other agencies regarding the who's who so that one agency isn't doing all the work. It will be more efficient and effective if all agencies work together / NICNAS publish a monthly bulletin advising of new issues that have arisen overseas on chemicals / Need a simple web interface that the public can click on which guides people to all the agencies eg. a link on the federal govt. Gateway website 'chemical safety'. Get rid of the jargon / Publish a monthly bulletin to inform where an assessment is at. - eg. status of the formaldehyde assessment with a time estimate.

10 am - 12 noon (FRIDAY 2 JUNE) The public may have fear of chemicals and a 'reasonable' non-specific publication on chemicals that has the general public as its target audience is required. The publication could include details of the general hazards of chemicals and their uses.

## PROPOSAL 2

SYDNEY MONDAY 15 MAY 2006

10 am - 12 noon Two years ok but nominations accepted any time

7 - 9 pm Looking at the list of chemicals to be assessed / Look at the mechanisms for seeking public nominations, eg. include local councils and precinct committees in advertising / The candidate list of chemicals should be available to the public for comment etc

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm Can't keep up with what NICNAS currently has to assess / Agreement to increase the frequency of call

7 - 9 pm Advertise on a more regular basis so that public can nominate chemicals, eg. Every six months. Advertise in local papers as well

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm General agreement

9 - 11 am (THURSDAY 18 MAY) Tell the public they can nominate chemicals at any time / General agreement

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm Need set intervals / Issue of confidentiality of nominators / Effects of chemicals – assessment of mixtures/synergistic effects / 2 years ok - how to manage expectations / NICNAS needs to consider how to respond to nominations / Need to maintain provision that chemicals can be nominated any time

7 - 9 pm 2 years reasonable but emphasise that chemicals can be nominated at anytime

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm Supported / Issue of by-products from previously assessed chemicals / Limit on time for NICNAS to respond to nominated chemicals

7 - 9 pm Supported / Target calls in future through contacts gathered in forums

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm Supported

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm General agreement

7 - 9 pm Annual call but at the same time publish a guide to how the public can nominate chemicals for review at any time

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm Need a good contacts list to publicise call / The call for nomination should be publicised better, using a wider range of media, including local papers, radio, e-mail subscriptions, TV.

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm Supported

9 - 11 am (THURSDAY 1 JUNE) *Noted that NICNAS has only completed less than 1% of the current work load/program; so why is NICNAS calling for more work?*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Call for nominations when the HVICL information is sought / Make it easier on the web to find out how to nominate chemicals. Include information on the data required to have a chemical prioritised for assessment. / NICNAS has a very low public profile and also with small chemical introducers*

11 am - 12 noon (FRIDAY 2 JUNE) *It was noted that a document is required that provides details of the guidelines for nominating a chemical, eg. the types of chemicals that would be assessed, what the type of information required to support the nomination, etc, and the nomination process.*

### PROPOSAL 3

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon *Need to capture environmental toxicants*

7 - 9 pm *Capture environmental toxicants / Reported that HSIS was not complete & contained errors*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Mechanism to orphan chemicals (remove from AICS) / Fee for companies to provide information*

7 - 9 pm *Prioritisation of review of unassessed chemicals*

DARWIN – TUESDAY 23 MAY 2006

7 - 9 pm *Supported*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Better link between HSIS list and NICNAS / It was noted that the chemicals on HSIS are considered hazardous and therefore their main concern is in the workplace*

CANBERRA – MONDAY 29 MAY 2006

7 - 9 pm *Anything on the HSIS should be assessed for other toxic end points including environmental*

### PROPOSAL 4

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon *Issue of mixtures and synergistic effects / Consider bioassays in assessments*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *Add sensitisers*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Need to consider body burden in criteria / Don't rely on just overseas studies / Note overseas research, eg. UK research on plastics/carcinogenicity / Requirement for NICNAS to respond to carcinogenicity issues*

7 - 9 pm *Supported*

DARWIN – TUESDAY 23 MAY 2006

7 - 9 pm *Need to consider mixtures of chemicals and possible synergistic effects / Consider chemical breakdown products - in body and environment / Need to respond to topical issues, eg. SLS*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *The categories should be expanded to include all lipophilic substances, chemicals with detoxification mechanisms; chemicals banned overseas, chemicals potentially found in breast milk and synthetic musk compounds*

HOBART – THURSDAY 1 JUNE 2006

9 - 11 am *It was suggested that the current screening categories should be expanded to include endocrine disrupting chemicals, neurotoxic chemicals, and those chemicals that cause epigenetic changes etc.*

MELBOURNE – FRIDAY 2 JUNE 2006

10 am - 12 noon *Add sensitisation - sensitisers were of particular concern in the workplace.*

### PROPOSAL 5

SYDNEY – MONDAY 15 MAY 2006

7 - 9 pm *Can we identify and assess toxic by-products and breakdown products? / What are the effects of mixing chemicals? / Public should be given more information regarding the safe handling of chemicals and incompatible chemicals, eg. advice on which chemicals shouldn't be mixed. / How does NICNAS identify high concern chemicals? Reported that Denmark has such a list of chemicals / AICS should be further annotated, so high concern chemicals can be identified and flagged. The Danish inventory has recently been annotated in this way. / Systems / databases that are used to screening-*

*reliability of data. / Generation of new data on existing chemicals – re animal testing - Who does the testing? / The need for new data on existing chemicals needs to be considered with the increased awareness/concern regarding animal welfare.*

**PERTH – TUESDAY 16 MAY 2006**

*2 - 4 pm How chemicals behave on earth compared with how they behave in outer space. Shouldn't use hazardous chemicals in outer space. / Nanoparticle emissions and chemicals produced as nanoparticles / Exposure from small particles / General agreement with proposals 3-5 / Annotate AICS to show which chemicals have not been assessed. All chemicals on AICS should show which chemicals have been assessed and which have not. NICNAS should declare that all chemicals are unsafe until proved otherwise.*

*7 - 9 pm Agreement / Consider anecdotal evidence*

**BROOME – WEDNESDAY 17 MAY 2006**

*7 - 9 pm General Agreement*

*9 - 11 am (THURSDAY 18 MAY) Interactions between chemicals in the environment needs to be considered / General agreement*

**ADELAIDE – MONDAY 22 MAY 2006**

*7 - 9 pm Note: use of Canadian information / Look at Canadian models/expertise to assist in short listing the 38,000 chemicals on AICS / NICNAS needs to spend money on resources to build up expertise on computer modelling/technology in Australia*

**DARWIN – TUESDAY 23 MAY 2006**

*2 - 4 pm If use Canadian model, need to take into account Australian conditions / Any external involvement in screening process?*

*7 - 9 pm Budget issues – how much will it cost? / Supported*

**TOWNSVILLE – MONDAY 30 MAY 2006**

*7 - 9 pm Nickel oxide powder was identified as a compound of concern and therefore potential future PEC / General support*

**CANBERRA – MONDAY 29 MAY 2006**

*2 - 4 pm Use data from workers compensation statistics / What tools are available to screen chemicals? eg. models, SAR, statistics. Potential in Australia to design specific tools / General agreement*

*7 - 9 pm Above should be taken as a package. Equating high volume to high risk is not necessarily correct. / Agents causing adverse human and environmental effects need to be fed into the screening process*

**BRISBANE – TUESDAY 30 MAY 2006**

*2 - 4 pm Prioritise on basis of risk / Difficulties noted in picking up chemicals in products, eg. brominated flame retardants in articles*

**HOBART – WEDNESDAY 31 MAY 2006**

*7 - 9 pm It was suggested that the interaction (synergistic effects) of chemicals should be considered when screening chemicals for assessment.*

*9 - 11 am (THURSDAY 1 JUNE) NICNAS should not spend time assessing chemicals already assessed, ie. there is no need to 'reinvent the wheel'.*

**MELBOURNE – THURSDAY 1 JUNE 2006**

*7 - 9 pm NICNAS make available SAR modeling training to industry so that industry can apply the structure-activity principles. Provide better modeling of sustainability / Clarify the proposals so that NICNAS will screen AICS according to published criteria. / Put more emphasis on chemicals that have not been assessed elsewhere, eg. overseas / If NICNAS does not assess chemicals that have been assessed overseas, does this mean that NICNAS accepts the overseas assessment? If so, this might not be a good thing.*

*10 am - 12 noon (FRIDAY 2 JUNE) Avoid duplication. It was suggested that NICNAS should not assess chemicals that have recently been assessed by another organisation (eg. WHO). Formaldehyde was cited as a chemical that has been extensively assessed by a number of international organisation/regulators.*

## **PROPOSAL 6**

**SYDNEY – MONDAY 15 MAY 2006**

*10 am - 12 noon Budget – where's money coming from? / Reporting needs to result in some action / How do you pick up chronic effects as well as acute?*

*7 - 9 pm Early warning signs important / Need to determine location of toxic chemicals*

- PERTH – TUESDAY 16 MAY 2006  
 2 - 4 pm *Use local data gathering systems / Include reporting of what chemicals are dumped at tips/ What is impact on the research sector, universities? / Voluntary/mandatory reporting / General agreement*  
 7 - 9 pm *Agreement*
- BROOME – WEDNESDAY 17 MAY 2006  
 7 - 9 pm *Adverse event reporting is needed / General agreement*  
 9 - 11 am (THURSDAY 18 MAY) *General Agreement*
- ADELAIDE – MONDAY 22 MAY 2006  
 2 - 4 pm *Have just one system for Australia / Issue of diagnosis / Discussions with HREOC, eg. MCS / Talk to APVMA / states etc for best model / Requires coordination across government / Need/use geographical integrated system (GIS) / Need to bring medical practitioners into any system (refer page 20) / Medical profession would be good information source — how to train them what to provide? / Education & awareness in schools?*  
 7 - 9 pm *Supported / Linkages of information / Analysis of current schemes, eg. APVMA / Issue of funding for community activities through government appropriation / Chemical users programs & awareness raising for users, eg. Mt Lofty program – emphasise importance of making contact with end-users / Effective communication mechanisms, eg. weekly newsletter/mail-out*
- DARWIN – TUESDAY 23 MAY 2006  
 2 - 4 pm *Supported / Awareness required in the health sector – coalescence of data and systems / Strong support for national reporting system / Maintaining database environmental and health sentinel events / Importance of feedback mechanisms*  
 7 - 9 pm *Strong support and should be co-ordinated federally / Mandatory reporting preferable / Make reporting as easy as possible so that people will use it*
- TOWNSVILLE – MONDAY 30 MAY 2006  
 7 - 9 pm *Recognised that local issues, ie. Environmental health impacts of chemical at local level, need to be fed into the assessment. / Communication between primary health practitioners, eg. local general practitioners, and NICNAS needs to be enhanced. For example, in Townsville area, a local medical practice has noted a 20%-30% increase in the incidence of asthma in local community. / NICNAS' ability to access medical records of individual exposed to chemicals under assessment needs to be increased. NICNAS needs to increase its use of these medical records. The privacy of individuals, however, must not be breached. / A question was raised as to where surveillance /monitoring data goes? Which department or organisation holds and maintains these data? Can the public access this data? If so where? It was noted that there are currently 16 chemicals for which monitoring data are required (OASCC health surveillance list) when they are used. What happens to this data?*
- CANBERRA – MONDAY 29 MAY 2006  
 2 - 4 pm *Could a scheme be extended to include not just adverse reactions? Need to be proactive as well as reactive in a reporting scheme. / General agreement*  
 7 - 9 pm *Linkage with air quality reporting scheme (NEPM – Victorian EPA). NEPM have a well-established surveillance system. / Need to consider burden on industry in reporting and providing the data. Discussion paper does not consider cost/benefit impact. / Industry has responsibilities and providing data is one of these.*
- BRISBANE – TUESDAY 30 MAY 2006  
 2 - 4 pm *Proposed that NICNAS function as a one-stop shop for adverse effects reporting. / Noted that the US has a good system for adverse effects reporting and could be used as a model. / Adverse effects reporting should include the monitoring of body burden of chemicals. Currently the US centre of disease control has such a system. / Longitudinal surveys should also be undertaken. Similar studies are undertaken in the UK. / The term 'surveillance' in the context of the proposal needs to be clearly defined. / 'Monitoring' above should include 'biological monitoring'*
- HOBART – WEDNESDAY 31 MAY 2006  
 7 - 9 pm *It was suggested that NICNAS should investigate options to encourage industry to introduce safer chemicals. One option suggested was NICNAS introduce increase the registration fees for those companies introducing hazardous chemicals, especially the more hazardous chemicals. / NICNAS should also look at the breakdown products of industrial chemicals and by products of industrial chemicals manufacture.*  
 9 - 11 am (THURSDAY 1 JUNE) *Reporting be restricted to high concern chemicals only. However it was also suggested that reporting not be restricted and all chemicals should be reported, regardless of use (ie. Industrial chemicals, pesticides, therapeutics). The latter, it was suggested, would allow earlier detection of trends and hazards. It was also noted that such reporting would need to be linked to other systems. / Noted that there are generally better controls for high volume chemicals and for those*

chemicals with recognised hazards - this should be kept in mind when developing screening protocols. / Need to develop checklists for regular reporting from companies that will feed into the reporting system. / The reporting system developed needs to be more user friendly than existing systems. The system should use, easy-to-use forms and allow self reporting by individuals adversely affected by chemical exposure, rather than relying on reporting by second party (eg. medical practitioner). / Any system needs to capture synergistic effects / Any system needs to be properly targeted

#### MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm NICNAS needs to pass adverse reaction data on to medical practitioners. / General practitioners need to be made aware of chemical exposure problems by, eg. A bulletin, and trained to recognise chemical exposure problems. / Other agencies (eg. OHS and environmental agencies, medical colleges) should feed into the adverse reaction scheme  
10 am - 12 noon (FRIDAY 2 JUNE) The term surveillance needs to be clarified or defined in the proposal. Any surveillance undertaken needs to be both health and exposure surveillance. It was acknowledged that there is inadequate information for both types of surveillance. / It was recognised that any data acquisition will need to have national perspective, ie. States and territories need to be included. / Need to consider overseas models. It was noted that the UK HSE conducts exposure studies and monitoring when this data isn't available. It was recommended that NICNAS include the UK HSE model in its review of current reporting systems. / It recommended that any reporting system should be designed in manner that will not breach the privacy of individuals. / It was noted that mandatory reporting may serve as a disincentive to companies collecting the monitoring data. / Suggested that NICNAS work with industry sectors. For example, It was noted that the oil industry undertakes lifelong health surveillance of its employees. / It was noted that there were cost implications for surveillance and monitoring programs and this needs to be considered, especially for large populations. It was also acknowledged that epidemiology provides information that often cannot be obtained by other means. / It was recommended that any reporting system should include contract workers, as these workers may be itinerant and may be missed in routine surveillance and monitoring programs. / It was acknowledged that 'event' exposure data are currently being collected by various organisations such as the fire services and EPA. The data just needs to be collated.

### PROPOSAL 7

#### SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon Institutional impediments to action – the vibe

7 - 9 pm Emphasise that direct enquiries are passed to the appropriate agency – part of who's who

#### PERTH – TUESDAY 16 MAY 2006

7 - 9 pm Assess replacements for chemicals that have been replaced / Motor fuels should be assessed

#### DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm Supported

#### TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm It was noted that often individuals looking for information on chemicals on the NICNAS website will be presented with a response 'chemical not found.' This doesn't assist users of the website, who frequently have to visit other websites to get more information. Information should be available, eg. if the chemical has been assessed, is it being assessed, if it is being assessed then what is the status of the assessment.

#### BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm One-stop shop approach for filtering / Needs support of better relationships with other agencies

### PROPOSAL 8

#### ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm If research required, who decides priority, eg. NHMRC Chemical research – which chemicals? Who does the research?

#### DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 pm - 9 pm Supported

#### TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm One participant noted that proposal 8 was the most important proposal so far.

## PROPOSAL 9

SYDNEY – MONDAY 15 MAY 2006

11 am - 12 noon and 7 - 9 pm *Supported / No strong comment*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *Anything giving more transparency is good / Perhaps resistance by suppliers to transparency General agreement*

7 - 9 pm *Shouldn't just look at science. Other warning signs need to be considered, eg. Observation in a clinical setting. / Can't say no problem if there's no scientific data / Common sense criteria need to be applied (Bradford hill criteria)*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm and 9 - 11 am (THURSDAY 18 MAY) *General agreement*

ADELAIDE – MONDAY 22 MAY 2006

7 - 9 pm *Proposals 7-9 supported / What can NICNAS learn from Canada etc?*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm (TUESDAY 23 MAY) *Supported / Ensure working party meets timelines etc*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *The rationale for assessing one chemical as a PEC over another needs to be articulated better by NICNAS. This will increase the transparency of the process. / The process and rationale for setting criteria needs to be more transparent.*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *General agreement*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *Priority be given to chemicals that are found in biological fluids, eg. breast milk / General support*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm and 9 - 11 am (THURSDAY 1 JUNE) *Supported*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Publish the criteria in plain English*

10 am - 12 noon (FRIDAY 2 JUNE) *Proposal 9 second sentence should read 'revised draft criteria'. Proposals generally supported. / Need to ensure that criteria are robust and defensible*

## PROPOSAL 10

ADELAIDE – MONDAY 22 MAY 2006

7 - 9 pm *Supported*

DARWIN – TUESDAY 23 MAY 2006

7 - 9 pm *Strong support / At annual reporting, companies should report all chemicals they are importing*

CANBERRA – MONDAY 29 MAY 2006

7 - 9 pm *Good idea*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *NICNAS should undertake joint programs with states and territories as means of enhanced information gathering. / Importers and manufacturers should be required to provide NICNAS with details of adverse effect reports they collect.*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Hard to support a proposal without knowing the scope of what powers are sought. Clarify what is wanted. / Time frames and timing when calling for information need to be greater and need to take into account company timing, eg. for budget. / Companies that have submitted data on time don't get any advantage over those who don't comply and non-compliers don't get penalised. / Simplify the data requirements, eg. allow estimates of volumes where there is a large number of products having small proportions of a priority existing chemical. / Criteria needed and clarify proposal, eg. Connection to proposal 17*

10 am - 12 noon (FRIDAY 2 JUNE) *Some concern was expressed over the extent of the broadening powers envisaged. It was suggested that there would be additional costs involved in providing the data and often the information is not available (eg. it may be held overseas and not easily obtained). / The types of data / information envisaged need to be clearly identified, eg. toxicological studies, exposure data, etc / It was recommended that NICNAS collect information on finished imported products, eg. cars, TVs, that can be considered as 'boxes of chemicals'. It noted that finished consumable products should also be considered, eg. the inks used in the packaging of consumables. The disposal of the packaging and inks needs to be considered.*

## PROPOSAL 11

PERTH – TUESDAY 16 MAY 2006

7 - 9 pm *'Chemical specific' basis is too narrow. Need to consider mixtures, and what might lead to an illness that cannot be traced to a specific chemical / Otherwise agreement*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm *How do we get information out of government agencies? / General agreement*

9 - 11 am (THURSDAY 18 MAY) *General agreement*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Change act / Formal arrangements and responsibilities for downstream users / Extended user responsibilities, eg. life cycle of the chemical (TV sets, tyres), closed loop*

7 - 9 pm *Clarify – volumes and locations of sale, eg. cleaning products, cosmetics / Need mechanisms to identify and communicate with downstream users*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm *Full support*

TOWNSVILLE MONDAY 30 MAY 2006

7 - 9 pm *Supported / Engage end-users to find what the chemicals are actually used for. / End users of a chemical needs to be engaged so that NICNAS can determine the actual use of a chemical. It is noted that sometimes chemicals may have a number of uses and a new use may be proposed by a downstream supplier.*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *Will universities be end-users? / General agreement*

7 - 9 pm *General agreement on proposals 10 & 11*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *Supported*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm *The wording of proposals 10 and 11 is not clear or not worded with sufficient strength. It was suggested that these proposals should indicate penalties. / Suggested that NICNAS establish a registry of downstream users of chemicals of concern.*

9 - 11 am (THURSDAY 1 JUNE) *These proposals were supported and it was suggested that they be mandatory. / It was noted that state and local governments could be considered downstream users in some cases / Need to indicate how information is being used in order to encourage provision of information / It was noted that for these proposals to be useful, there was need for adequate follow up on the information provided and that adequate resources be allocated to the activity.*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Engaging downstream users on individual chemicals will be difficult because they use products and suppliers are reluctant to disclose the ingredients. Chemicals that aren't classified or don't have say exposure standards are not disclosed on MSDS / Allow free registration for downstream users to encourage their participation in the system. This 'free' registration might need to be paid for out of government funds, not out of current registration fees. / Difficult processes are a disincentive for industry*

10 am - 12 noon (FRIDAY 2 JUNE) *It was noted that NICNAS is considered at times 'academic'. It was noted that, while this was beneficial at times, a lack of industrial experience can result in unrealistic requests for additional information. Therefore, greater industry awareness is required within NICNAS to allow better and focussed information gathering.*

## PROPOSAL 12

SYDNEY – MONDAY 15 MAY 2006

7 - 9 pm *How do you identify a chemical that should be subject to secondary notification? More information should be provided to industry and the public regarding how to identify the secondary notification conditions for a chemical that has been assessed by NICNAS. / Industry support however difficulties perceived in identifying chemicals / Customers may not inform suppliers of new uses of a chemical / What are the penalties for not obeying recommendations concerning secondary notification?*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm and 7 - 9 pm (WEDNESDAY 17 MAY) *General agreement*

BROOME – THURSDAY 18 MAY 2006

9 - 11 am *General agreement*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm *Supported / Need to go back and look at usage of assessed chemicals*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Supported*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *General agreement*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *Generally supported*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm *It was suggested that this should not be a blanket approach to secondary notifications and that the proposal be applied on a case-by-case basis. Ideally, the proposal should state 'where appropriate'.*

9 - 11 am (1 JUNE 2006) *Supported*

MELBOURNE – FRIDAY 2 JUNE 2006

10 am - 12 noon *Supported*

### **PROPOSAL 13**

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Need education and awareness in schools*

7 - 9 pm *Need regular summits of all major agencies across all levels of governments / State dept of health role for MOU group*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm *Engagement would follow during discussion on controls and powers of control / Issue of coverage for smaller states/territories – have a lot of ground to cover with limited resources – chemicals tend to have lower priority / Need to consider local issues across the country – there might be demographic and geographical issues / Issue of having a summit – good idea, limit time / Use of chemical in NT may be different to use elsewhere in Australia*

7 - 9 pm *Supported / Need to get all agencies involved in NICNAS processes*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *It was noted that often end users don't know who to talk to in government, eg. which level of government is responsible for what? / NICNAS is encouraged to publish a list of laboratories that can undertake independent testing of chemicals eg. if an end-user or an individual who is exposed to a chemical would like a toxic soil sample tested, where do they go?*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *Is there an intent to actually put obligations on states & territories regarding chemicals management & to engage them in the process?*

BRISBANE - TUESDAY 30 MAY 2006

2 - 4 pm *Mechanisms for obtaining information/data from state and territory agencies should be examined by NICNAS.*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm *Suggested that the current MOU agreements be expanded to include local governments.*

MELBOURNE – FRIDAY 2 JUNE 2006

10 am - 12 noon *Need to avoid duplication in reporting of issues*

### **PROPOSAL 14**

PERTH – TUESDAY 16 MAY 2006

7 - 9 pm *The public should not be the watchdog*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm *Supported*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Suggested that 'ensure' be amended to 'enforce'.*

10 am - 12 noon (FRIDAY 2 JUNE) *Need to ensure that safer and better technologies are encouraged and not stifled by the legislation.*

### **PROPOSAL 15**

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *Should use overseas assessments*

ADELAIDE MONDAY 22 MAY 2006

7 - 9 pm *Supported*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm *Supported / Issue of accepting OECD assessments and need to adapt for Australia*

7 - 9 pm *Supported / Leverage overseas information*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Use of overseas assessments – information could be published more quickly*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *Exchange NICNAS staff & overseas agencies staff*

7 - 9 pm *Useful to provide information to stakeholders on how international treaties affect chemical usage, eg. Implementation of SAICM at a national level. Exchange of information on Australian compliance with international treaties. Make sure overseas information is relevant to the Australian situation eg. persistence in the environment*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *NICNAS needs to increase the number of links it has on its website to other websites that contain chemical information / There is a need to harmonise it/computer systems used by organisation involved the regulation of chemicals*

HOBART – THURSDAY 1 JUNE 2006

9 - 11 am *Australia is a small country so we should pick up what has been done in other countries*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Why can't NICNAS simply adopt an assessment someone else has done? / Suggested that NICNAS adopt an international assessment as an interim measure while conducting a NICNAS review*

## **PROPOSAL 16**

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon and 7 - 9 pm *Supported / Seen as the most important proposal*

PERTH – TUESDAY 16 MAY 2006

7 - 9 pm *General agreement*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm and 9 - 11 am (THURSDAY 18 MAY) *General agreement*

DARWIN – TUESDAY 23 MAY 2006

7 - 9 pm *Supported*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Supported / NICNAS needs to have more open conversations with countries that we can trust*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm *Talk to the RACI for input & expertise on chemistry / General agreement*

7 - 9 pm *Clarify reach of bilateral arrangements, ie. Information exchange & using o/s assessments*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm and 9 - 11 am (THURSDAY 1 JUNE) *Supported*

## **PROPOSAL 17**

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon *Trigger mechanisms for quick response / What are legal implications? / Practicality and implementation timeframes and responsibilities for implementing recommendations*

7 - 9 pm *Need to respond quickly, acknowledged / Supported*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm and 7 - 9 pm *General agreement*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm *Can't take short cuts in chemical assessment. Would not like to see assessment shortened only for the sake of assessing more chemicals. Don't compromise quality for the numbers / General agreement*

9 - 11 am (Thursday 18 MAY 2006) *Information report should not mean that a full assessment couldn't be done later if thought necessary / General agreement*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm and 7 - 9 pm *Supported / 350 page reports too long – ability to digest information*

*Don't make like MSDS – ensure relevant to employees - single sheet/placed in lunchroom etc - eg. Chemwatch / Consider consultation prior to preparation of information sheets*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm and 7 - 9 pm *Supported / Need timeframes for assessments*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *Generally supported*

CANBERRA – MONDAY 29 MAY 2006

2 - 4 pm and 7 - 9 pm General agreement / Degree of assessment needs to be related to the degree of risk

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *Need for a consolidated list of existing guidelines and codes of practices for labels and MSDS – put on website / Consumer right-to-know - members of the public need to access MSDS and other related information on the chemicals that are used in workplaces and in public buildings. An example was cited of an individual who was not able to visit her GP as the practice had just been treated with pesticide. The GP was not willing to provide details of the chemicals that were used. / Noted that there are difficulties associated with assessing individual chemicals in products and this should be examined.*

HOBART – WEDNESDAY 31 MAY 2006

7 - 9 pm *Supported*

9 - 11 am (THURSDAY 1 JUNE 2006) *Noted that greater flexibility was needed in the types of data that can be accepted as supporting evidence in the setting of an exposure standard. It was suggested that UK has a model that can be used as a guide.*

MELBOURNE – THURSDAY 1 JUNE 2006

7 - 9 pm *Need to be able to quickly assess a chemical that is in the media to either confirm problems or provide advice to the public that there is no cause for concern / Keep all parts of documents consistent / People should be able to specifically request NICNAS for assistance on a fee for service basis for particular problems / Link proposal 17 with proposal 10 (information requirements)*

10 am - 12 noon (FRIDAY 2 JUNE) *Supported*

## **PROPOSAL 18**

SYDNEY – MONDAY 15 MAY 2006

7 - 9 pm *Criteria for banning a chemical need to be developed and used / Appears that the NICNAS assessment process is informative enough to take such action / Could replace states and territories legislation / Banning too severe in some cases, eg. some laboratory chemicals*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *NICNAS should ban a whole lot of unsafe chemicals / Banning could cause problems for research, eg. Obtaining calibration standards*

BROOME – WEDNESDAY 17 MAY 2006

7 - 9 pm *Why can a chemical be banned overseas yet still be used in Australia?*

ADELAIDE – MONDAY 22 MAY 2006

2 - 4 pm *Federal government should pick up entry point of chemicals in control / Promote in public media the effects of certain chemicals*

7 - 9 pm *Supported / Need to manage risk as well as ban/restrict / Encourage use of substitutes, eg. for asbestos*

DARWIN – TUESDAY 23 MAY 2006

2 - 4 pm *Banning may be difficult if chemical used in multiple sectors*

7 - 9 pm *Fully supported / Powers to ban critical, eg. asbestos*

TOWNSVILLE – MONDAY 30 MAY 2006

7 - 9 pm *It was noted that chemicals that have been banned overseas have been found in use in Australia. It is not clear why this was allowed to happen / It is not clear what is happening in Australia with old stockpiles of expelled chemicals*

BRISBANE – TUESDAY 30 MAY 2006

2 - 4 pm *Does Australia import chemicals, which are banned overseas?*

## **PROPOSAL 19**

SYDNEY – MONDAY 15 MAY 2006

10 am - 12 noon *Provision for input of data from all sources, eg. environmental, financial etc to make a decision to ban / Advise other jurisdictions to restrict under their legislation / National approach needed for graduated restrictions, eg. phase-outs, bans but states/territories to legislate*

7 - 9 pm *Requires consultation and a nationally consistent approach by states and territories agencies. Restriction to certain people supported*

PERTH – TUESDAY 16 MAY 2006

2 - 4 pm *These give NICNAS the powers the APVMA has. This is a must do. Don't have to rely on other agencies doing something.*

7 - 9 pm *Onus should be on introducers to show safety of a chemical / General agreement*

**BROOME – WEDNESDAY 17 MAY 2006**

7 - 9 pm *Need more control over who chemicals are sold to, eg. pesticides / Control of disposal.*

*Subsidy for disposal for remote areas / General agreement*

9 - 11 am (THURSDAY 18 MAY) *Chemicals identified to be high hazard or risk should be banned or controlled at a national level / General agreement*

**ADELAIDE – MONDAY 22 MAY 2006**

2 - 4 pm *Extra powers for NICNAS supported / Need to consult with states and territories – NOHSC model?*

7 - 9 pm *Naming and shaming supported, but in association with other measures, eg. financial fines need to be large to be effective*

**DARWIN – TUESDAY 23 MAY 2006**

2 - 4 pm and 7 - 9 pm *Fully supported / Support for greater regulation of chemical use / Take-up of controls may still not be fully effective, eg. experience with APVMA model*

**TOWNSVILLE – MONDAY 30 MAY 2006**

7 - 9 pm *Supported / A need for national consistency with regards to the control/regulation of hazardous chemicals was recognised. The need was most apparent in the case of ammonium nitrate, where there are different requirements in each state / The controls for hazardous chemicals need to be published by NICNAS.*

**CANBERRA – MONDAY 29 MAY 2006**

2 - 4 pm *There is currently a big gap in current systems that articles are not regulated / Good to have exemptions for research if a chemical is banned / A permit system to allow use of the chemical for general research rather than a licensing system for specific research use is preferable. / General agreement*

7 - 9 pm *Agree with both proposals. The scheme needs teeth.*

**BRISBANE – TUESDAY 30 MAY 2006**

2 - 4 pm *Strongly supported*

**HOBART – WEDNESDAY 31 MAY 2006**

7 - 9 pm *Suggested that NICNAS encourage substitution when more hazardous chemicals are used and/or the phase out of these chemicals. / NICNAS provide advice of alternatives to the more hazardous chemicals that are currently in use and/or the phase out of these chemicals*

9 - 11 am (THURSDAY 1 JUNE) *Need to encourage industry towards safer technologies / It might be better to include 'naming and congratulating' companies that use safer chemicals/technologies as measure by which NICNAS can increase its powers to control. / More detail was needed on how NICNAS intended to enforce and monitor all the measures given in proposal 19, eg. infringement notices. / NICNAS needs to consult/engage with local government when developing and implementing these proposals, as enforcement may be required at the local government level, eg. Would local government need to be trained up?*

**MELBOURNE – THURSDAY 1 JUNE 2006**

7 - 9 pm *Need to avoid duplication, eg. Licensing powers. Would a national licensing body mean state licensing would not be needed? / Don't have a level playing field. Suppliers who don't do the right thing have a financial advantage over those who do. Good idea to have power to recall supply and prosecute illegal supply. / Recognise suppliers who do the right thing*

10 am - 12 noon (FRIDAY 2 JUNE) *National regulation is better than separate regulation by individual states and territories. This would simplify chemical regulation and reduce costs. Supported by industry and community at the meeting. / It is appropriate for NICNAS to become the central chemical regulator. / Any new regulation or legislation should not duplicate existing regulation/legislation in the states and territories or other federal agencies. / Any changes in regulations or legislation should not be purely a power grab by NICNAS. / Proposals need consideration of enforcement powers also. / Funding NICNAS' increased powers may be substantial.*

## **PROPOSAL 20**

**SYDNEY – MONDAY 15 MAY 2006**

10 am - 12 noon *'Clear action statements,' mean different things to different people so need more explanation.*

7 - 9 pm *Some recommendations should be written as regulations rather than recommendations as they need to be more binding.*

**PERTH – TUESDAY 16 MAY 2006**

2 - 4 pm *Assessment of chemicals is useless if uptake of recommendations is voluntary*

7 - 9 pm *It's critical to have the ability to implement recommendations / NICNAS must involve all stakeholders in its decision making process / General agreement*

- BROOME – WEDNESDAY 17 MAY 2006  
7 - 9 pm and 9 - 11 am (THURSDAY 18 MAY) *General agreement*
- ADELAIDE – MONDAY 22 MAY 2006  
7 - 9 pm *Need for consultation at early stages / Forums for consumers to ascertain issues*
- DARWIN – TUESDAY 23 MAY 2006  
2 - 4 pm and 7 - 9 pm *Supported / Need to promote benefits of recommended actions to community and states and territories*
- TOWNSVILLE – MONDAY 30 MAY 2006  
7 - 9 pm *Supported*
- CANBERRA – MONDAY 29 MAY 2006  
2 - 4 pm *NICNAS should provide options in regulating a chemical following assessment. / Engage the different regulators during the assessment process / General agreement*  
7 - 9 pm *Recommendations should not allow for interpretations - they should be clear and practicable*
- HOBART – WEDNESDAY 31 MAY 2006  
7 - 9 pm *Supported*  
9 - 11 am (THURSDAY 1 JUNE) *Noted that a one-stop shop chemical regulator would be ideal - would allow broader engagement with the public / It suggested that NICNAS publish a list of approved chemicals similar to the list of food additives published by FSANZ. / It was noted that there was a need for a federal clearinghouse for chemicals to review the work and programs developed by state governments – would be better for consumers. / It was noted that there is shortage of trained environmental health officers currently employed in government.. / This is of concern, as environmental health officers may need to implement/enforce NICNAS recommendations.*
- MELBOURNE – THURSDAY 1 JUNE 2006  
7 - 9 pm *Each community engagement forum (CEF) representative should be required to demonstrate they have taken chemicals issues from NICNAS back to their constituent groups / NICNAS forms need to have a separate contact details section.*  
10 am - 12 noon (FRIDAY 2 JUNE ) *Suggested that NICNAS work in partnership with the states and territories on various projects. The ASCC work with states and territories was cited as an example that could be used as a model. / If uptake of recommendations works well, and MOU with other agencies effective (federal and states and territories), then additional powers by NICNAS may not be required*

## **GENERAL ISSUES RAISED**

- SYDNEY – MONDAY 15 MAY 2006  
10 am - 12 noon *How many chemicals have been assessed under the existing chemicals program, and what action has been taken? / How big is the budget? / What is the scope of the scheme, eg. are incidentally produced chemicals covered (eg. dioxins)? / Can past events be covered in the scheme, eg. exposure of a renovator working on a house with lead paints? / How can NICNAS encourage use of safer chemicals, particularly as many older chemicals are cheaper and relatively easy to purchase?*  
7 - 9 pm *Storage issues at Port Botany – federal or state responsibilities? / Lack of co-ordination between government agencies / Need simpler regulation for chemicals / Assessment of poisons / Need a one-stop shop for labeling requirements – common guidelines.*
- PERTH – TUESDAY 16 MAY 2006  
2 - 4 pm *Why can people buy dangerous chemicals, not read the label and use them inappropriately, especially using pesticides contrary to the label directions? / There is inconsistent implementation of standards such as exposure and health, across the states, particularly WA / Health issues of toxicity from synergies of chemicals in mixtures and the environment / Impact of any regulatory change on local government / Impossible to keep up with regulatory changes. Regulators don't talk to each other. / Dealing with research quantities of chemicals / Database based on CAS numbers which will link to all regulation Australia-wide / Use of precaution in assessment and taking into account those who might be extra sensitive. MCS. / Effect of synthesising chemicals and paperwork required. Impact of thresholds on (bona fide research) / Disposal cost built into chemicals upfront / New chemicals process is very expensive. Newer chemicals are often safer and the NICNAS process can prevent safer chemicals being introduced. Make process easier. / Control on domestic disposal, eg. backyard burning. Upfront cost would lead to dumping costs being free so disposal will be better. Upfront cost will make chemicals more expensive so people will use professionals rather than use chemicals inappropriately. / Tax of 38 cents/litre on solvents due to come in July 2006. Where did this come from, what's it about? / Extend submission deadline to 8 July 2006 / Public believe if products are on sale they are safe / Hazards of mixtures / The public is empowered if people know what chemicals have not been assessed. They can then choose to buy the product or not. / Use/misuse of chemicals by the*

public / Only have diluted products available not the concentrated forms / Exposure standards aren't sensitive enough and work to the detriment of the public Chemicals may be present in levels within guidelines but in combination they behave differently. We can't just look at individual chemicals and just at the toxicology. Clinical evidence needs to be taken into account. Not all people react in the same way / Information at point of sale on chemicals / Later introducers of chemicals to provide a rebate to the initial introducer of a new safer chemical. / Numbers of people affected by chemical is usually small. Surveys don't pick up problems in small populations so surveys are actually tools to suppress the real information / Chemicals assessed and shown to be safe should be able to display a recognised logo, eg. a green tick / PBDE levels in breast milk in Australia are 5 times higher than in Europe / NICNAS should assess degradation products of chemicals as well as the parent chemical / Clinical and epidemiological data should be used in assessments

**BROOME – WEDNESDAY 17 MAY 2006**

7 - 9 pm What happens with chemicals in combination especially in the environment? / Labelling problems on sheets of MDF. Warnings are painted on the side of the stack but once sheets are removed, part of the warnings is also removed. / Some sections of the public are at higher risk because information doesn't get to them, eg. aboriginal communities. Could need targeted education.

**ADELAIDE – MONDAY 22 MAY 2006**

2 - 4 pm Multi-chemical sensitivity / Endocrine disruptors – phthalates / Leadership issue of Australia – role in international forums – most research conducted overseas / Resources / End-use products – does NICNAS assess? / Use of overseas assessments / Wastewater treatment chemicals / Control by states/territories / Adverse effects / Risk assessment model - broaden to consider social impacts – link to human rights / Body burden analysis program – relevant to proposal 2 / Safety standards/acceptable standards – based on political considerations / Standards can be used inappropriately, eg. exposure standards – different reactions / Alternatives to hazardous chemicals – pesticides/spread / Local government issues – how are they considered in assessment? eg. air quality / Cosmetics covered by NICNAS / NICNAS assesses chemicals not products / Some cosmetic products may contain a mixture of chemicals of concern / Validate AICS list (38 000 chemicals) / identify those chemicals in use and not in use (orphan chemicals) / Issue of labelling and MSDS for domestic chemicals

7 - 9 pm Awareness of NICNAS's work - not readily known / Comparison NICNAS-APVMA powers / NICNAS awareness of change in use of a chemical / How is NICNAS funded?

**DARWIN – TUESDAY 23 MAY 2006**

2 - 4 pm NICNAS web site useful / Keep web links updated (eg DEH gateway) / No harmonisation of regulation between states/territories / Issue of importing and lack of controls, eg. for chemicals in products / Issue of Australian customs service (ACS) and what's coming in – compliance and recognition of chemical names and lack of training for ACS staff / Formal arrangement with Canada / NICNAS needs to have sufficient resources / Darwin has low level of industrialisation

7 - 9 pm Dental services – issues of legislation in NT not consistent with other states, eg. disposal of chemicals down sink / Issue of underground water table in NT / Issue of usage of chemicals and risk assessment / Issue of suitable substitutes for some disinfectants, eg. Glutaraldehyde / MSDS – comment on poor standard of some MSDS and lack of information on long-term health effects

**TOWNSVILLE – MONDAY 30 MAY 2006**

7 - 9 pm Need better link between HSIS list (OASCC) and NICNAS - looking at a one-stop-shop, eg. concerns on exposure standards could come to NICNAS / Only a small number of chemicals that are used daily have been assessed by NICNAS – call for sodium hypochlorite to be assessed / There needs to be better enforcement of workplace controls, eg. the use of fire blanket to prevent leaks / Who approves chemicals for retail use?

**CANBERRA – MONDAY 29 MAY 2006**

2 - 4 pm How will the proposals impact on universities and research? / Extension of time requested for submissions

7 - 9 pm How do water quality guidelines fit in with NICNAS, eg. consideration of health impacts of what is found in water.

**BRISBANE – TUESDAY 30 MAY 2006**

2 - 4 pm Community right to know / Import of hazardous wastes / Labelling of domestic products and chemicals / The need for a one-stop shop for chemical regulation and information – needs a lead agency

**HOBART – THURSDAY 1 JUNE 2006**

9 - 11 am Interest in MSDS preparation noted / Hazards of non-active ingredients in products need to be assessed

MELBOURNE – THURSDAY 1 JUNE 2006

*7 - 9 pm Need a forum, eg. NICNAS, for assistance with hazard classification (like a peer review). A fee-for-service arrangement was proposed – suggested that this proposal be addressed in the review. / Compliance of MSDS with the Australian requirements is poor and this is not being enforced. / AICS needs to be audited in relation to generic CAS numbers. / Putting HSIS list on web and not publishing a hard copy means union safety reps don't have access. / AICS should indicate if a chemical is a hazardous substance and/or a dangerous good and/or environmentally hazardous. What proportion of existing chemicals are hazardous substances and/or dangerous goods and/or environmentally hazardous?*

*10 am - 12 noon (FRIDAY 2 JUNE) What has been the effect/impact of NICNAS chemical reviews to date? / Need consistency in the legislation. For example it was stated that polymers in the 'raw' form could not be introduced easily by industry (for a number of reasons) but are introduced in finished articles.*

## APPENDIX 7: ADDITIONAL ISSUES IDENTIFIED DURING THE REVIEW

Both in written submissions and at public forums, substantial general comment was received. In both cases, some comment was outside the scope of the review, however, most comment was relevant. A number of comments concerned chemical regulation in general, but were considered outside the scope of the review.

In general the comments at the public forums and in written submissions were highly supportive of the reform proposals in the Public Discussion Paper because of the perceived benefits they would bring to the community, industry and government through a more effective and efficient Existing Chemicals Program. The community overwhelmingly supported all proposals whereas industry and some government bodies were more circumspect in that some proposals required amplification and further consultation with stakeholders. In general, government was supportive of the reform proposals which are consistent with other proposed government reforms, eg. the EPHC's framework for National Chemicals Environmental Management (NChEM).

At both the public forums and in written submissions, comments of a general nature were raised, some of direct relevance to the review and some of relevance to NICNAS and general chemical regulation but outside the scope of the review.

An analysis of relevant issues is summarised below.

### COMMENTS RELEVANT TO THE REVIEW

#### General chemicals regulation

Comment was received at public forums and in written submissions that Australia needs a lead regulator for industrial chemicals. In some cases, the concept of a 'one-stop shop' was proposed. The current regulatory framework for industrial chemicals is perceived as complex and not necessarily uniform across the nation, resulting in difficulties for industry in compliance and difficulties for the community in accessing and receiving appropriate information.

Two industry written submissions and one from a government agency suggested that some of the proposals required more detail and consultation with stakeholders and, due to their possible impact on other chemicals regulation, should be referred to the COAG Ministerial Task Force. The possible impact of the proposals in the Discussion Paper on other government agencies was raised in several government written submissions.

Some comment in written submissions suggested that NICNAS is currently perceived as reactive rather than being proactive.

#### Emerging health and environmental issues

A number of specific issues were raised during the public forums and in written submissions, eg. multi-chemical sensitivity (MCS). While comment on these issues did not relate to a specific proposal in the Discussion Paper, they are regarded as relevant to the Existing Chemicals Program, eg. NICNAS is currently participating in work on MCS in a whole-of-government approach to this issue.

Similarly, one written submission commented that the Discussion Paper did not mention nanomaterials. As for MCS, NICNAS is currently participating in work on nanomaterials in a whole-of-government approach to this issue.

#### Susceptible populations

Comment was received in a number of submissions that the impact of industrial chemicals on susceptible populations, eg. children and the unborn, be considered in the NICNAS assessment process.

NICNAS as part of its commitment to undertake world's best practise risk assessment is continually examining assessment methodologies, processes and tools to better identify and assess risks to susceptible populations from industrial chemicals.

#### Assessment of mixtures

One written submission focussed on the effects of mixtures of chemicals and presented arguments for the toxicological testing of mixtures rather than individual chemicals, based on potential synergistic or potentiating effects. It recommended that NICNAS give priority to the effects of mixtures of chemicals in its assessments as humans are exposed to a number of chemicals in the environment rather than a single chemical.

The effect of mixtures of chemicals was raised as a concern at a number of public forums, with concern for the potential harmful effects of a mixture compared to the harmful effects of the individual components.

## **ISSUES OUTSIDE THE SCOPE OF THE REVIEW**

The following issues were raised during the Review, however, the RSC determined that they were outside the scope of NICNAS and that they be referred to other government agencies.

### **Ingredient disclosure in labelling of domestic chemicals**

The labelling of chemical products available to the public was identified as a concern during the focus group consultations and during the public comment phase at public forums and in written submissions. Unlike cosmetics, most domestic chemical products do not carry a full list of the ingredients on the label. In the interests of availability of chemical safety information to the public, it has been suggested that full disclosure of ingredients on labels would lead to greater transparency and enhanced confidence in the safety of chemical products available to the public.

This matter is to be referred to the secretariat of the National Drugs and Poisons Scheduling Committee in the Office of Chemical Safety.

### **Material Safety Data Sheets (MSDS)**

The variable quality of MSDS was raised as a concern at the public forums. In addition, the possibility of NICNAS acting as a repository and approving authority for MSDS was raised during the focus group consultations. While recognising the importance of MSDS as hazard communication tools in the use and control of hazardous substances, such a role is outside the remit of NICNAS. Nevertheless, NICNAS is committed to the preparation of sample MSDS for the chemicals assessed in its Existing Chemicals assessment program.

This matter is to be referred to the Office of the Australian Safety and Compensation Council.

### **Funding**

Comment was received at public forums and in written submissions that additional government funding be provided to enhance its Existing Chemicals Program. NICNAS is a cost-recovered agency and its sources of funding are not subject to review in this instance.

### **General policy issues**

In a written submission, it was suggested that NICNAS develop a clearly stated set of ethical principles, stating that these may be useful in guiding decision-makers when potential conflicts of interest arise. Decisions taken in NICNAS are governed by the Act, a Service Charter and a Community Engagement Charter. The Director of NICNAS, a ministerial appointee, is the sole decision-maker whose level of accountability is absolute. NICNAS staff are accountable to the Director under the Act and all committees are bound by confidentiality arrangements.

### **Enforcement of international standards**

In a written submission, it was recommended that NICNAS enforce the WHO international standards for volatile organic compounds, eg. in homes, public places, personal care products and transport.

Air quality standards in Australia are set by the Environment Protection and Heritage Council, with enforcement by the relevant state and territory environmental agencies. This matter will be referred to the relevant agencies.

### **Stockpiles of old chemicals**

Concern was raised at public forums about the stockpiles of old chemicals and their options for disposal. It was felt that NICNAS should play a central role in resolving this issue and that strong regulation was needed to control risks to health and environment.

The management of stockpiles of industrial chemicals is undertaken by the relevant state and territory agencies. This matter will be referred to the NICNAS - states and territories Memorandum of Understanding (MOU) committee for advice and referral to the appropriate agencies.

## APPENDIX 8: SUBMITTERS TO THE REVIEW

This is a listing of submitters who responded to *Promoting safer chemical use: towards better regulation of chemicals in Australia – a discussion paper for public engagement on a new model for the NICNAS Existing Chemicals Assessment Program (April 2006)*

- 1 ACCORD Australasia Ltd
- 2 Airwatch QLD
- 3 Allergy, Sensitivity & Environment Health Association QLD Inc
- 4 Australian Chemical Trauma Alliance (Anne Want)
- 5 Australian Chemical Trauma Alliance (Betty Moore)
- 6 Australian Council of Trade Unions
- 7 Australian Government Department of the Environment and Heritage
- 8 Ruggero Benevenuti
- 9 Nina Bishop
- 10 Clare and Iain Bradbeer
- 11 Des Brooker
- 12 Rhonda Brooker
- 13 Mrs C Buckley
- 14 Peter & Maureen Byl
- 15 Community Taskforce on Multiple Chemical Sensitivities (WA)
- 16 Mary Clark
- 17 Ray Deighton
- 18 Department of Employment and Workplace Relations
- 19 Department of Environment and Conservation NSW
- 20 Department of Human Services Victoria
- 21 Win Dockter
- 22 Doctors for the Environment Australia
- 23 Ms Diane Dunbar
- 24 Econeco Pty Ltd
- 25 Environment House
- 26 Environment Protection and Heritage Council's Chemicals Working Group
- 27 EPA Victoria
- 28 Peter Evans

- 29 Food Intolerance Network
- 30 Con Georgantis
- 31 Katrina Gosschalk
- 32 Health Consumers' Council WA Inc
- 33 Nancy Hillier
- 34 Ms Marice (Maggie) Lyons
- 35 M Kay Mays
- 36 Therese Meyer
- 37 Minerals Council of Australia
- 38 Wendy Murray
- 39 National Toxics Network
- 40 Nick Pastalatzis
- 41 Plastics and Chemicals Industries Association
- 42 Dr John K. Pollock
- 43 B Prideaux, A Culhane, E Prideaux, D Walker, E Ames, J Francis, L Crackpool, W Saedder, J Riley
- 44 Christopher Purcell
- 45 RMIT University (Applied Science)
- 46 RMIT University (Toxicology)
- 47 Annie Rutter
- 48 Jan Schmidt
- 49 The Chamber of Minerals & Energy (WA)
- 50 The Royal Australian Chemical Institute Inc
- 51 Victorian Trades Hall Council
- 52 Mrs VM Vogel
- 53 Ms Heather Webb
- 54 WA Department of Environment
- 55 Worksafe Victoria
- 56 NICNAS Community Engagement Forum