NICNAS submission to the Productivity Commission Study into Chemicals and Plastics Regulation October 2007

Executive Summary

The introduction of industrial chemicals into Australia is governed by the National Industrial Chemicals Notification and Assessment Scheme, under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and associated regulations. The scheme began in 1990. The control of use of industrial chemicals from sale, downstream and end use and disposal are a matter for state/territory agencies. The movement of certain hazardous industrial chemicals in and out of Australia is also subject to international treaty arrangements.

NICNAS is a chemical entity-based notification and pre-market risk assessment scheme. Industrial chemicals are defined in the context of their use and by their exclusion as therapeutic goods, food/food additives, pesticides and veterinary medicines. The scope of the NICNAS risk assessment comprises three elements, occupational health and safety, public health and environmental impact, over the full life cycle of the chemical.

NICNAS has the mandate to assess new and existing industrial chemicals under the framework set out under the Act. NICNAS exemption and assessment categories for new chemicals include a risk based gradient for data requirements, permissible introduction volumes and ultimately their listing on the national inventory. Existing chemicals are assessed in response to health and environmental concerns.

The NICNAS assessment identifies risks to human health and the environment from current/intended use(s) of industrial chemicals. NICNAS's risk assessment outcomes include recommendations to agencies with regulatory/standard setting responsibilities for industrial chemicals (including NICNAS), recommendations or mandatory conditions of use to industry, imposition of post-market responsibilities on introducers and chemical safety information dissemination. Under current regulatory arrangements, two approaches are used to impose restrictions on use: conditions on introduction and control of use. Restrictions on use of a chemical can be imposed by mechanisms such as annotation of the chemical on the national inventory, states/territory regulations, listing on prescribed international treaties or through national standards for cosmetics (only).

Non-statutory arrangements are in place for OHS and public health recommendations arising from NICNAS assessments to be considered for adoption in a consistent manner into state/territory law. To facilitate this process, NICNAS recommendations are framed in accordance with nationally agreed frameworks and guidelines. Currently, no mechanism exists for nationally consistent consideration of NICNAS's environmental recommendations. The Environment Risk Management Framework for Chemicals developed under the auspices of the Environment Protection and Heritage Council is addressing this issue. NICNAS assessment information is available to state and territory agencies to assist in regulating the control of use, release and disposal of industrial chemicals.

NICNAS is proactively addressing concerns related to duplication of regulatory effort, variations in data requirements and inconsistencies in assessment approaches, through a range of national and international harmonisation strategies. Outcomes of nationally/internationally agreed assessments and assessment methodologies are utilised in the NICNAS assessment programs.

NICNAS works cooperatively with all its stakeholder groups: industry, governments and the community. Co-regulatory and cooperative initiatives are utilised by NICNAS for low risk chemicals. These provisions are balanced by post-market obligations on the introducers such as record keeping and annual reporting. NICNAS also recognises the range of industry self-regulatory initiatives aimed at managing the risks arising from the use of industrial chemicals.

It is acknowledged that regulatory systems cannot operate only through primary and subordinate legislation alone. While recognising the regulatory effort expended by regulators and the industry must be commensurate with the risks posed by these chemicals, NICNAS also recognises the importance of government accountability and maintenance of public confidence in the regulatory system. The challenge therefore, is to identify the correct balance between black letter law and co- and self- regulatory approaches that will deliver acceptable outcomes to all stakeholders.

NICNAS has been very responsive to stakeholder concerns and emerging issues and has consistently moved to increase the efficiency and effectiveness of the regulatory system. NICNAS regulatory reforms are specifically aimed at promoting the introduction of safer chemicals, technological innovation, and a streamlined pathway to commercialisation onto the Australian market. These reforms afforded significant tangible and intangible benefits to industry and the community.

Early reforms included low volume exemptions for new industrial chemicals within specified risk parameters, permit categories for early introduction of less hazardous chemicals and chemicals for commercial trials, broadening of acceptance criteria for polymers of low concern consistent with international trends, cooperative mechanisms to utilise previous NICNAS authorisations and electronic notification templates.

Significant reforms to the scheme were introduced in 2004, under the Low Regulatory Concern Chemical (LRCC) reforms. These reforms introduced flexibility into the assessment process to enable the fast tracking of low regulatory concern chemicals while maintaining existing levels of worker safety, public health and environmental standards. A major outcome of the LRCC reforms was the new regulatory arrangements for products at the cosmetic –therapeutic interface. More recently NICNAS has embarked on a review of its existing chemicals assessment program and a review of the regulatory framework for disinfectants in Australia.

NICNAS reforms have afforded significant benefits to the chemicals and plastics industry while maintaining or enhancing health, safety and environmental standards. These reforms are benchmarked against international best practice and aim to harmonise regulatory requirements with major trading partners, where possible. NICNAS continues to reform its programs in response to stakeholder concerns and emerging issues within the context of COAG principles and guidelines.

1. The Australian Industrial Chemicals Regulatory Framework

The current system of overall chemicals management operates within a complementary, whole of Australian Government framework, and consists of a range of national and state/territory agencies. Within this framework, the introduction of industrial chemicals (through importation or manufacture) is governed at the Australian Government level by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The scheme is established under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act)[1] and Industrial Chemicals (Notification and Assessment) Regulations 1990 (regulations)[2].

Control of use of industrial chemicals is governed by relevant state/territory legislation. The movement of certain hazardous industrial chemicals in and out of Australia is also subject to international treaty arrangements such as the Rotterdam Convention.

The Act provides for:

(a)a national system of notification and assessment of industrial chemicals for the purposes of:

(i) aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals; and

(ii) providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals; and

(iii) giving effect to Australia's obligations under international agreements relating to the regulation of chemicals; and

(iv) collecting statistics in relation to the chemicals; and

(b) national standards for cosmetics imported into, or manufactured in, Australia and the enforcement of those standards.

The Act clearly differentiates between the powers of the Director, NICNAS and the Minister. It also specifies those decisions of the Minister or the Director that may be taken before the Administrative Appeals Tribunal (AAT), which is the only safeguard mechanism for challenging decisions made under the Act.

Notification and assessment framework

Under the Act, an industrial chemical is defined by exclusion, that is a chemical is deemed to be an industrial chemical when it has an industrial use, whether or not it also has an excluded use. Excluded uses are pesticides, veterinary medicines, therapeutic goods and food additives. This definition presents interfaces with other Australian Government regulatory authorities and NICNAS has established mechanisms to work cooperatively with these agencies.

NICNAS is a chemical entity-based notification and risk assessment scheme (ie NICNAS does not register products (mixtures of chemicals)). NICNAS assesses

industrial chemicals in the context of their use. The scope of the risk assessment comprises three elements; occupational health and safety (OHS), public health and environmental protection over the full life cycle of the chemical. The policy responsibility for each of these sectors resides with the following Australian Government portfolios: Health and Ageing (public health), Employment and Workplace Relations (OHS), Environment and Water Resources (environment). There is no single whole of government policy for the regulation of industrial chemicals.

NICNAS's assessment role in chemicals contained in articles is dependent on the method of their introduction into Australia. Articles themselves are excluded from the operation of the Act, however, chemicals released from articles can be subject to NICNAS assessment. In addition, if an article is manufactured in Australia NICNAS requirements would apply to the chemicals used in its manufacture.

Linkage between federal and state/territory regulations
Non-statutory arrangements are in place for OHS and public health recommendations arising from NICNAS assessments to be considered for adoption in a consistent manner into state/territory law. This occurs through an intermediate step, a review by the Office of the Australian Safety and Compensation Council (OASCC) for OHS recommendations and the National Drugs and Poisons Schedule Committee (NDPSC) for public health recommendations. Neither the decisions of the OASCC nor the NDPSC are legally enforceable, rather they are designed to facilitate nationally consistent standards for workplace and consumer chemicals, respectively, that can then be adopted by relevant state and territory legislation.

To facilitate this process, NICNAS OHS recommendations are framed in accordance with nationally agreed frameworks, the National Model Regulations for the Control of Hazardous Substances in the Workplace and the National Dangerous Goods Framework. The National Model Regulations and Dangerous Goods standards are adopted through a range of mechanisms into jurisdictional control of hazardous substances and/or dangerous goods legislation or primary OHS Acts. Similarly, NICNAS's public health recommendations are framed in accordance with NDPSC guidelines, for inclusion as national standards on the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP is adopted by state and territory poisons, drugs and controlled substances legislation. Jurisdictional legislation allows for non-adoption, partial adoption or adoption with amendment of national standards.

Currently, no formal mechanism exists for nationally consistent consideration of NICNAS's environmental recommendations. Each state/territory environmental agency determines whether and how to implement NICNAS's environmental recommendations. The Environment Risk Management Framework for Chemicals (NChEM) developed under the auspices of the Environment Protection and Heritage Council is addressing this issue. See Section 2 for further details.

The information from NICNAS assessments is available to state and territory agencies to assist in regulating the control of use, release and disposal of industrial chemicals and to support the wide range of chemicals management legislation for the protection of human health and the environment. NICNAS has a formal relationship with

states/territories through their membership on the NICNAS States/Territories Memorandum of Understanding Group. In all cases states/territories have nominated OHS agencies to this group. Informal links exist with public health and environmental agencies both directly and through the MoU Group.

Regulatory powers

The Act and associated regulations confer certain regulatory powers on the Director or the Minister for the purposes of introduction of industrial chemicals. The processes by which these regulatory powers are to be exercised are explicitly outlined in the Act. These regulatory powers include:

- The Minister - to make national standards for cosmetics imported into or manufactured in Australia;
- The Minister - to authorise the introduction of a new chemical before assessment in the public interest within specific conditions;
- The Minister – where there are reasonable grounds to believe that a particular activity in relation to a priority existing chemical (eg import or manufacture) poses an unacceptable risk to human health or the environment, the Minister may prohibit that activity until the outcome of the assessment is known;
- The Director - to issue permits authorising the introduction of new chemicals within specific conditions;
- The Director - to include particulars in respect of a chemical on the Australian Inventory of Chemical Substances (AICS), including conditions of use;
- The Director - power to prohibit or restrict the introduction or export of industrial chemicals to give effect to Australia's obligations under international agreements relating to industrial chemicals;
- The Director – to require certain post market activities from introducers of industrial chemicals such as notification of significant changes in circumstances of the use of an assessed chemical, provision of annual reports on volumes and adverse effects from chemicals introduced under NICNAS exemptions, permits and self-assessments

International obligations

The Act gives effect to Australia's obligations under international agreements[3] through regulatory powers to prohibit or restrict the introduction or export of industrial chemicals.

NICNAS implements import and export restriction for industrial chemicals listed under the Rotterdam Convention. Liaison with state/territory regulatory agencies facilitates the coordination of information at a national level enabling Australia to meet its obligations for notifying the Convention of any chemicals that are banned or severely restricted[3].

Consistent with the requirements under the Stockholm Convention, NICNAS takes into account persistence, bioaccumulation and toxicity characteristics of chemicals when conducting assessments on new and existing chemicals.

Collection of statistics

NICNAS collects statistics and other information on industrial chemicals such as industrial chemicals used in high volumes in Australia and makes this information publicly available[4]. NICNAS also collects use information on specific industrial

chemicals and information on the volumes and adverse health and environmental effects (if any) of chemicals introduced under exemptions, permits and self-assessments. This information is published in NICNAS Annual Reports.

Advice mechanisms

The Act does not provide for statutory mechanisms to advise the Director, NICNAS. Instead, NICNAS has established several non-statutory and informal mechanisms through which input is obtained from stakeholder groups. Three non-statutory bodies representing the main stakeholder groups provide advice on the operation of the scheme: The Community Engagement Forum (CEF) assists in addressing the community's 'right to know' in relation to the control and use of industrial chemicals, especially in the areas of worker health and safety, public health and the environment. The Industry Government Consultative Committee (IGCC) oversees the efficient and effective utilisation of NICNAS resources and the scheme's operational performance. The State/Territories Memorandum of Understanding (MOU) group acts as a conduit between NICNAS and state/territory OHS, public health and environmental agencies.

NICNAS has also established a Technical Advisory Group (TAG) that provides advice to the Director on applications for listing of chemicals on the confidential section of the AICS. NICNAS also convenes committees/technical groups as required, to provide advice on specific issues.

NICNAS Registration

Introducers of industrial chemicals are required to be registered with NICNAS. NICNAS maintains and publishes the Register of Industrial Chemicals Introducers. Registration enables NICNAS to identify legitimate introducers of industrial chemicals and to provide information on chemicals regulation to all introducers that in turn facilitates compliance with the requirements of the Act.

Conclusion

The mechanisms to be used by NICNAS in order to meet the objectives of the Act are explicitly stated throughout the Act, including the specific powers of the Director and the Minister. The use of exclusions to define an industrial chemical present interfaces with other sectors such as therapeutic good, food, pesticides and veterinary medicines. While the scope of NICNAS assessments is clearly specified, there is no clear legislative mechanism whereby NICNAS recommendations for managing risks from the use of the chemical are translated into state/territory law. While informal mechanisms exist for national standard setting bodies to review and make further recommendations to OHS and public health state/territories agencies, uptake of such recommendations rests with each jurisdiction. The Environment Risk Management Framework for Chemicals (NChEM) is addressing the lack of a framework for the adoption of NICNAS's environment recommendations.

The Act does not provide for statutory mechanisms to advise the Director, NICNAS. Instead, NICNAS utilises a range of non-statutory and informal mechanisms to obtain input from other government agencies, industry and the community in relation to its activities.

2. Notification and assessment of industrial chemicals

NICNAS follows best practice risk assessment/risk analysis procedures to achieve the safe and sustainable use of chemicals. This concept is based on:

- sound and credible science;
- minimum regulation required to achieve health, safety and environmental outcomes;
- avoidance of duplication;
- risk based decisions;
- inclusive processes and practices;
- transparent and consistent approaches; and
- availability of chemical safety information tailored to stakeholders needs.

NICNAS is charged with providing chemical safety information to the public. This requirement must be balanced with protection of commercially sensitive information. The Act includes confidentiality provisions that enable commercially sensitive information that could reasonably be expected to prejudice commercial interests to be withheld from publication.

The Act is explicit about circumstances under which such an exemption may be exercised, and commercial interest must outweigh the public interest. For example, general information that identifies the chemical such as the name by which it is known to the public, its general uses, health, safety and environmental information and NICNAS recommendations to enable its safe use cannot be exempt from publication.

NICNAS assessment reports on new and existing chemicals are published on the NICNAS website and summary reports are also published in the *Chemical Gazette*. These assessments provide information on the chemical's physicochemical properties, toxicity and ecotoxicity profile, characterisation of human health and the environmental risks arising from the intended use of the chemical and recommendations for safe use.

Since NICNAS was established in 1990 and to June 2007, the agency has assessed over 2000 new chemicals under certificate categories and in the order of 1700 new chemicals under permit categories**.** During this period NICNAS has also assessed approximately 180 existing chemicals. These were assessed as single chemical assessments or group assessments and they include priority existing chemical assessments, secondary notifications and a range of other assessment products.

New 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

It is an offence under the Act to introduce a new industrial chemical into Australia without a valid NICNAS assessment certificate or permit. This does not apply to certain chemicals introduced under NICNAS exemption categories, which are of relatively low risk, introduced in small volumes or subject to high levels of control or restricted access. Exemptions include:

- chemicals introduced at volumes below the exemption threshold of 100 kg per year that pose no unreasonable risk to human health or the environment;
- chemicals introduced at volumes below the exemption threshold of 100 kg per year and used solely for research, development or analysis;
- chemicals in transit that remain subject to the control of Customs at the port or airport; and
- non-hazardous chemicals introduced in a cosmetic at a concentration of 1% or less provided other specified safeguards were met.

While chemicals that meet these exemption criteria do not require pre-market assessment, this exemption is balanced with post market reporting obligations such as record keeping and annual reporting requirements.

New chemical notifications result in the issuing of assessment certificates and permits. The NICNAS permit system provides a means of by-passing the assessment certificate system for chemicals used in relatively low volumes, limited circumstances such as a single or few workplaces undertaking commercial trials or used in circumstances where the use, handling and disposal of the chemical is highly controlled. In all cases, specific safeguards are defined.

The Act specifies data requirements for individual permit and certificate categories and outlines the assessment process and contents of assessment reports. In general certificate applications require a more comprehensive data set than permit applications and, consequently, permissible introduction volumes and durations are usually greater under certificates than permits. Within certificate categories, the nature of the chemical and proposed annual introduction volumes generally dictate the assessment category and hence the data set required.

Chemicals assessed under certificate categories are listed on the national inventory, AICS, 5 years after assessment, unless the company requests immediate listing. Chemicals assessed under permit categories are not added to the AICS[5]. Once the chemical is listed on the AICS, it is available for widespread use within use conditions, where specified.

Existing chemicals

Currently, there are over 38,000 existing industrial chemicals in Australia, that is, chemicals listed on AICS. Since 1977 the government provided several opportunities for industry to nominate chemicals in commerce for inclusion on AICS, including a 5-year period under the then Department of The Arts, Sport, Environment, Tourism and Territories. In addition, a 2-year amnesty period was declared in 1993 during which time the AICS was opened up again. When nominating chemicals to be listed on the inventory, applicants were required to provide information about the chemical, based on agreed criteria to support the request for AICS listing.

NICNAS assesses exiting chemicals on a priority basis based on health and/or environmental concerns. Anyone can nominate chemicals to NICNAS for priority review. NICNAS also has a formal public nomination process. All nominations are screened against agreed selection criteria and those chemicals that meet the required

criteria are listed for review. NICNAS also undertakes assessments of particular aspects of chemicals in response to emerging concerns.

Assessment outcomes

New chemical certificates and existing chemicals

There are five possible outcomes from NICNAS assessments for new chemical certificates and existing chemicals:

- Recommendations to other agencies to implement control measures
- Regulatory action by NICNAS through annotation of the chemical on the AICS
- Recommendations to industry on the use of the chemical
- Post-market responsibilities on introducers such as notification of changed circumstances of use and annual reporting obligations for chemicals introduced under NICNAS exemptions, permits and self-assessed certificates.
- Dissemination of chemical safety information

New chemical permits

In contrast, the Act enables NICNAS to impose conditions of use on new chemicals used under NICNAS permits. NICNAS has the role of monitoring compliance with these conditions and the Director has the power to revoke permits.

Best practice assessment and methodology

No statutory peer review mechanisms are available to NICNAS. However, NICNAS uses a range of quality assurance mechanisms such as:

- internal (NICNAS) peer review of all assessments;
- national and international external peer review based on relevant expertise;
- review by the Advisory Group on Chemical Safety that was established to provide technical and scientific advice in the fields of regulatory science as they relate to human health and safety for veterinary, agricultural, industrial and domestic chemicals[6].

Benefits of international harmonisation

Concerns have been raised about the duplication of assessment effort, variations in data requirements for assessment and inconsistencies in regulatory approaches across national and international regulatory authorities. These concerns have led to a call for greater national and international harmonisation.

Recent reports to government recommended international harmonisation as a key mechanism for reducing these aspects of regulatory burden. These included the:

- Australian Chemicals and Plastics Industry Action Agenda Steering Group Report *Underpinning Australia's Industrial Growth Report to Government* (October 2002)[7]; and
- Report Of The Taskforce On Reducing Regulatory Burdens On Business: *Rethinking Regulation* (Banks Review)[8]

In response to these reviews the government committed to reducing unnecessary regulation and to 'uniquely Australian' variation of international standards being contingent on a demonstration of net public benefit. This commitment included

working towards the development and recognition of internationally acceptable standards for data generation and assessment through international bodies, approval of overseas industrial chemical schemes of equivalent standards and implementing aspects of the Globally Harmonised System (GHS) for hazard classification and labelling of chemicals.

NICNAS plays a key role in Australia's efforts to advance international harmonisation of practices and approaches to the assessment of industrial chemicals as well as acceptance of international assessments. As there is no international standard setting body for industrial chemicals. NICNAS uses two strategies in it's international harmonisation efforts.

(a) multilateral forums established under the auspices of the Organisation for Economic Development and Cooperation (OECD), the World health Organisation (WHO)/International Program on Chemical Safety (IPCS) and the Asia-Pacific Economic Cooperation (APEC) forum; and

(b) bilateral arrangements with various overseas regulatory agencies.

International harmonisation affords benefits to all stakeholders and as such has the support of industry and the community. For regulatory agencies these include:

- saving scientific resources through the acceptance of assessments from overseas agencies with comparable assessment standards;
- providing greater access to external scientific expertise and methodologies;
- potential for collaboration on emerging issues of international concern such as nanotechnology and perfluorinated chemicals;
- expanding national perspectives on industrial chemical notification, assessment and risk management processes and practices.

For industry:

- Reducing regulatory costs associated with data generation, preparing and submitting notifications;
- Reducing time to introduce or market new chemicals where international assessments can be utilised to determine low concern categories;
- Access to incentives such as fee rebates under NICNAS Approved Foreign Scheme provisions;
- Assessment processes that are internationally consistent.

For the community harmonisation affords:

- equivalent standards of health, safety and environmental protection; and
- greater access to chemical safety information.

NICNAS's scientific expertise is recognised and acknowledged internationally in leadership roles performed by NICNAS staff. NICNAS staff have made a significant contribution to the international harmonisation effort through influencing decisions to align with national priorities and contributing their scientific and regulatory expertise. The primary focus of NICNAS's activities are summarised below:

(a) (i) OECD activities

New chemicals

The OECD New Chemicals Taskforce agrees common data sets and report formats and facilitates co-notification of assessments.

Current projects of relevance are:

- The Mutual Acceptance of Notification (MAN) Parallel Process project will increase understanding of assessment approaches and facilitate mutual acceptance of hazard assessments amongst participating OECD member countries. Australia, through NICNAS, has been the lead country for three of six chemicals nominated under the project and secondary country for the other three.
- Work on definitions, exclusions and exemptions to harmonise key regulatory definitions and a common approach for substances which are either exempt from notification or subject to reduced regulatory requirements in member countries. Australia, through NICNAS, is leading the review of low concern polymer (PLC) criteria, identifying commonalities and differences within national regulatory schemes for polymers that will culminate in the development of common PLC criteria.

Existing chemicals

Activities under the OECD Existing Chemicals Program include:

- Screening Information Data Set Initial Assessment Meetings (SIAM) that develops Screening Information Data Sets (SIDS) for health and environmental hazard information of existing chemicals. These hazard assessments are utilised by NICNAS in its national assessment program. To date approximately 30 SIDS have been utilised in various existing chemicals assessment products.
- Investigating the health and environmental effects of perfluorinated chemicals (a class of chemicals of international concern), and harmonising regulatory approaches to their assessment. NICNAS's leadership resulted in a list of perfluorinated chemicals in global commerce, that is a resource for all OECD member countries to identify chemicals within this class that may be in use in their own jurisdictions. This work also facilitated the development of a NICNAS position on this class of chemicals.

Nanotechnology

NICNAS is a member of the OECD Working Party on Manufactured Nanomaterials, which enables Australia to keep pace with research into potential human health and environmental impacts of this emerging technology that will facilitate Australia's regulatory responses to this novel technology. Australia, through NICNAS, leads a project to develop an international database on human health and environmental safety research and is involved in safety testing of a representative set of manufactured nanomaterials. Collectively these international activities will enhance knowledge and facilitate a regulatory response that is commensurate with any risks posed by manufactured nanomaterials.

(a) (ii) WHO/IPCS

Australia through the Department of Health and Ageing, Office of Chemical Safety, chairs the IPCS Harmonisation Project[9] Steering Committee and the Department of Health and Ageing has committed to adopt all best practice methodology from this project to facilitate greater transparency and use of international assessments in its national regulation program.

NICNAS participates in a range of IPCS projects. They include:

- Cancer risk assessment
- Exposure assessment
- Skin Sensitisation in Chemical Risk Assessment
- Concise International Chemical Assessment Document (CICAD) program[10].

NICNAS consistently uses methodologies agreed at the IPCS in its own risk assessments. These include the Conceptual Framework for Considering Mode of Action of Chemical Carcinogenesis and the Glossary of Key Exposure Assessment Terminology. CICADs are internationally accepted reviews of human health and environmental effects of chemicals that also provide exposure estimations and risk characterisation that can be applied at a national level. Information from CICADs is utilised in NICNAS's existing chemicals assessments with 5 NICNAS assessments incorporating CICAD information to date.

(a) (iii) APEC

NICNAS participates in the Asia-Pacific Economic Cooperation (APEC) forum, particularly the Chemical Dialogue Steering Group. The dialogue focuses on the impact of international chemicals regulation, including the EU REACH assessment program and GHS, and explores opportunities for enhanced cooperation in the Asia-Pacific region.

(b) Bilateral arrangements

NICNAS also draws on the work undertaken by counterpart agencies in those countries that have established similar mechanisms for notification and assessment of industrial chemicals.

The NICNAS assessment framework shares aspects of the European scheme that operated at the time the scheme was established. Common features for chemicals (excluding polymers) are:

- chemical entity based scheme;
- risk based decisions;
- information (data) driven;
- pre-market notification and assessments; and
- inclusion of hazard classification for the purposes of labelling.

The EU REACH scheme, effective from June 2007, incorporates some distinct features that differ from NICNAS, however, the basic principles remain unchanged. EU scheme did not assess polymers and this position remains unchanged under REACH.

The US scheme is also a chemical entity-based risk assessment scheme. However, notification is only required pre-manufacture. No pre-determined data requirements apply for assessment and no hazard classification is undertaken. NICNAS has adopted the US polymer exemption criteria for its Polymer of Low Concern category.

The Canadian notification and assessment scheme for industrial chemicals has significant similarities to NICNAS. Notable exceptions are:

- no occupational health and safety component in its risk assessments;
- no hazard classification.

(i) Canadian New Substances scheme

NICNAS has proactively sought to develop links with the Canadian industrial chemicals regulatory scheme because of the similarities between the two schemes, particularly assessment methodologies and strategies (noting however that Canadian assessments do not include an OHS component). These similarities have provided a good platform for working cooperatively since 1999 to gain an understanding of and confidence in each other's assessment processes and procedures.

This work has culminated in recognition of the Canadian New Substances Regulations as an approved foreign scheme under the Act , which enables NICNAS to adopt the Canadian hazard assessments in our own risk assessments.[11 12]

Direct benefits to industry from this arrangement are:

- free early introduction permits for chemicals assessed as low concern polymers in Canada; and
- 40% reduction in assessment fees when Canadian assessment reports are provided with the notification.

Australian and Canadian authorities are exploring opportunities to extend this cooperative arrangement to existing industrial chemicals.

(ii) New Zealand

NICNAS and the New Zealand Environmental Risk Management Authority (ERMA) have a Memorandum of Understanding (MoU) that establishes a co-operative relationship between the parties in connection with industrial chemicals which may also be hazardous substances[13]. The *Hazardous Substances and New Organisms Act 1996* under which industrial chemicals are regulated in New Zealand has some significant differences when compared with the NICNAS scheme. In the main, the New Zealand Environmental Risk Management Authority (ERMA) is a product approval and registration scheme (some chemicals are also approved by ERMA) as distinct from NICNAS's solely chemical entity based scheme.

In addition, ERMA only approves and registers industrial chemicals that are hazardous substances. New Zealand utilizes the Globally Harmonised System (GHS) system for hazard classification, which differs from Australia's Workplace Hazardous Substances classification system. The NICNAS scheme requires all new industrial chemicals to be notified irrespective of their hazard status with recommendations being proportionate to the risk posed by their use.

In 2004-05, the Trans Tasman Mutual Recognition Arrangement (TTMRA) commitment was taken between Australia and New Zealand to progress work to resolve the special exemption for industrial chemicals through a five-year work plan. This work plan, conducted under the NICNAS and the New Zealand ERMA MoU**,** will determine which elements of the Australian and New Zealand schemes could be mutually recognised or harmonised. While structural issues have been identified as impediments to mutual recognition for industrial chemicals, opportunities for harmonisation and cooperative work have also been recognised.

National harmonisation
NICNAS is also an active and influential participant in activities at the national level that aim to achieve consistent approaches in assessments across governments, as appropriate, as well as ensuring that emerging issues that have wider ramifications are dealt in a whole of government manner.

Benefits from national harmonisation include:

- saving scientific resources through acceptance of other national assessments in NICNAS assessment program and utilisation of NICNAS's assessments by other regulators.
- providing greater access to external scientific expertise and methodologies;
- potential for collaboration on emerging issues of national concern such as nanotechnology and endocrine disrupting chemicals;
- greater potential for data sharing;
- co-notification across a range of regulators.

Science forum

The Science Forum for best practice approaches to health risk assessment was established as part of the government's response to the Chemicals and Plastics Action Agenda Steering Group Industry Report, *Underpinning Australia's Industrial Growth.* The Forum considers current regulatory assessment practices and methods among participating agencies, international trends and harmonisation of best practice risk assessment methodology. It brings together regulatory agencies within the Health Portfolio, the Therapeutic Goods Administration (TGA), NICNAS, Office of Gene Technology Regulator (OGTR) and the Food Standards Australia New Zealand (FSANZ). In addition it includes regulatory/standard-setting agencies from other portfolios such as the Australian Pesticides and Veterinary Medicines Authority (APVMA), the OASCC and the Department of the Environment and Water Resources (DEW).

National Nanotechnology Strategy

NICNAS is participating in activities under the National Nanotechnology Strategy coordinated by the Australian Department of Industry, Tourism and Resources. Of particular note is NICNAS's role in the cross-portfolio working group on health, safety and environment (HSE) issues (see section 5 for details).

NChEM

NICNAS participates in the environmental reform program under the EPHC National Chemicals Taskforce into the ecologically sustainable management of chemicals in Australia – the National Chemicals Environmental Management framework

(NChEM). Several of the NChEM proposals mirror recommendations in the report of the NICNAS Existing Chemicals Program review (see section 5 for details).

Globally Harmonized System (GHS) for classification and labelling of chemicals
Chemicals assessed by NICNAS include a hazard classification in accordance with both the Approved Criteria for Classifying Hazardous Substances (under the Australian National Model Regulations framework) and the GHS criteria.

Of the 142 new chemicals assessed and subjected to hazard classifications by NICNAS between July 2004 and June 2007, 81 chemicals were classified as hazardous to human health according to the Approved Criteria for Classifying Hazardous Substances and the GHS criteria. Of these 81 chemicals, 28 were also classified for environmental hazard under the GHS system. Under the Approved Criteria only human health hazards warrant classification for occupational health and safety.

Hazard classifications were conducted during the same period for nine existing chemicals. Five of these were classified as hazardous to human health under both systems and one was classified as hazardous to the environment under GHS.

This work will form part of the ongoing situational analysis of the potential for the implementation of GHS in Australia in the future.

Bilateral activities
Bilateral collaboration on individual chemicals assessments and assessment methodology occurs with the TGA, FSANZ and APVMA. A significant collaborative activity between TGA and NICNAS was the recently completed reforms of products at the cosmetic-therapeutic interface. Disinfectant reforms that have just commenced are a future collaborative activity between these agencies (see section 5 for details).

Additional to these reform activities NICNAS has consulted with the TGA, APVMA and FSANZ on individual assessments of chemicals that are used across a range of regulatory sectors such as the polybrominated flame retardants, sunscreen agents, water treatment chemicals and food contact chemicals.

Exposure to some chemicals can occur from several sources such as food, water, and consumer products. Recent assessments of dioxins and flame retardants are examples of concurrent assessments undertaken by several regulatory authorities on specific chemicals.

Conclusion
In conclusion, NICNAS has the mandate to assess new and existing industrial chemicals and make recommendations for their safe use or impose conditions under which the chemicals must be used in order to ensure health, safety and environmental standards are maintained. The Act and regulations set out the framework within which NICNAS's notification and assessment functions must be undertaken. NICNAS utilises a range of strategies to facilitate national and international harmonisation on a multilateral and bilateral basis. This ensures Australia can influence the direction of these programs to serve national interests and minimise uniquely Australian requirements. Input into technical forums influences the quality

and outcomes of nationally/internationally agreed assessments and assessment methodologies that can be utilised in the NICNAS assessment programs.

3. Conditions on introduction and control of use of industrial chemicals

The NICNAS assessment identifies risks to human health and the environment from current/intended use(s) of industrial chemicals through their full life cycle, ie manufacture/import, transport, storage, formulation into products (mixtures), end use and disposal. If conditions/restrictions on use are warranted, two approaches are available under current regulatory arrangements, conditions on introduction and conditions to control use.

1. Conditions on introduction

Restrictions on use of a chemical can be imposed through five mechanisms. These are:

- NICNAS annotation of the chemical on the inventory with conditions of use;
- NICNAS recommendations to ban or restrict use effected through states/territory regulations via recommendations to national standard setting bodies such as the NDPSC or ASCC;
- Listing of the chemical on prescribed international treaties, which are treaties to which Australia is a signatory;
- For cosmetics, the Minister may determine national standards;
- For Priority Existing Chemicals that are believed to pose an unacceptable risk to human health and/or the environment, the Minister may ban/restrict use temporarily and pending the outcome of the NICNAS assessment.

(a) AICS annotation

Where the risk assessment demonstrates an overall risk from the use of a chemical, NICNAS can regulate the introduction of that chemical through inclusion on the AICS of condition(s) to which the importation or manufacture of the chemical is subject. The process whereby such AICS annotations are applied is explicitly outlined in the Act and penalties apply for breaches of conditions of use.

Where NICNAS imposes a condition of use on a chemical on the AICS, it is legal to introduce the chemical within the restrictions of the particular annotation without notification to NICNAS. If the chemical is to be used outside these restrictions, it must be notified to NICNAS as a new chemical for assessment prior to introduction. In effect, an annotation on the AICS delineates between a new and existing industrial chemical and is not a total prohibition on introduction.

(b) State/territory regulations

The states/territories have the power to ban or restrict chemicals. Mechanisms to facilitate consistent approaches by states/territories are:

- national processes such as the National Model Regulations and/or Dangerous Goods framework for chemicals used in the workplace via ASCC;
- prohibiting use of certain chemicals in consumer products through listing on Appendix C of the SUSDP.

(c) International treaties
The Director can regulate the movement of industrial chemicals that are subject to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. Import or export of industrial chemicals listed under the Rotterdam Convention are subject to authorisation by the Director, NICNAS (some exceptions apply).

(d) National standards for cosmetics
The Act enables the Minister, by legislative instrument, to make national standards in relation to cosmetics imported into or manufactured in Australia. The Cosmetics Standard 2007 is the first national standard to be made under this provision. Penalties apply for con-compliance with these national standards.

(e) Restrictions on priority existing chemicals while the chemical remains under assessment
Temporary bans/restrictions may be imposed by the Minister, where there is reasonable grounds to believe that a particular activity in relation to a priority existing chemical poses an unacceptable risk to human health or the environment. Such a ban/restriction is effective only until such time the outcome of the assessment is known.

2. Control of use - state/territory responsibility
Where relevant, the NICNAS assessment includes recommendations for risk minimisation after import or manufacture. Under current regulatory arrangements these recommendations have no legal force. Such measures are subject to further consideration by either the ASCC or NDPSC, for OHS and public health recommendations, respectively. The outcome of those considerations is enacted by various mechanisms into state/territory law.

Currently, environmental recommendations are provided directly to states/territories who then determine how they may be adopted and implemented, although reforms to this process are being considered by NChEM. Once adopted into state/territory law it is the responsibility of the respective agencies to implement risk management measures and to monitor compliance.

Consumer product safety falls within the jurisdiction of the *Trade Practices Act 1974* and the responsibility of the ACCC and state/territory Departments of Fair Trading. Labelling of cosmetic products is also governed by and enforced under the *Trade Practices Act 1974.*

Conclusion
Collectively the Act/regulations, international treaty arrangements and state/territory regulations facilitate regulatory controls to be implemented where such a need is identified through NICNAS assessments. While under the Act there are some regulatory powers vested in the Director and the Minister, they relate to introduction of the chemical. All control of use from sale, downstream and end use and disposal are a responsibilities of state/territory agencies.

4. Co-regulatory, self-regulatory and consultative approaches to the management of industrial chemicals

NICNAS works cooperatively with all its stakeholder groups. Industry stakeholders are consulted predominantly through industry organisations such as ACCORD Australasia, the Plastics and Chemicals Industry Association (PACIA), the Australian Paint Manufacturers' Federation (APMF) and the Australian Chamber of Commerce and Industry (ACCI), who are all represented on the NICNAS Industry Government Consultative Committee.

Similarly, NICNAS works cooperatively with the community predominantly through the NICNAS Community Engagement Forum (CEF). Its membership includes the three NICNAS assessment sectors, public health, occupational health and safety and the environment. The Principles in the NICNAS Community Engagement Charter are applied to all NICNAS activities.

The IGCC also includes representatives from Australian Government portfolios: DoHA, DEWR and DEW, which facilitates consultation across Australian Government agencies. The MoU with states/territories is the formal mechanism for liaising with state/territory regulatory agencies.

Co-regulatory and cooperative initiatives
During the recent Low Regulatory Concern Chemicals (LRCC) reforms, all stakeholders agreed that an effective compliance program must underpin NICNAS's activities in order to maintain industry and public confidence in the scheme. Industry members also wanted the assurance that the industry's reputation is not harmed by the actions of those businesses who fail to comply with current regulatory requirements.

Opportunities were identified to reduce the regulatory compliance burden on industry though a co-regulatory approach. Many industry members already comply with voluntary codes of practice, which in some cases can require higher standards than regulatory requirements. The LRCC Taskforce also recognised public concerns that co-regulation can undermine public confidence in the industry as well as the regulatory scheme. The LRCC Taskforce recommended that NICNAS, industry and the community investigate opportunities and the feasibility of introducing effective co-regulatory approaches where appropriate in relation to industrial chemicals regulation[14].

In 2004, LRCC reforms introduced audited self-assessments into the mix of assessment options available to industry. Self-assessments prepared by industry are accepted for low concern chemicals and polymers. The benefits to industry from this reform are:

- lower cost self-assessment notification categories;
- reduced data requirements; and
- shorter statutory assessment timeframes that result in reduced time to market.

In order to maintain community confidence in the safety of self assessed chemicals, industry is required to:

- retain supporting data for 5 years report; and
- report annually to NICNAS on adverse health and environmental impacts.

At this time, NICNAS also increased existing exemption thresholds and introduced new exemptions (all within specific criteria) enabling industry access to greater volumes and a greater range of new chemicals without pre-market assessment. This change is balanced by the requirement for industry to retain records for 5-years and provide annual reports to NICNAS.

A more recent example of a cooperative activity between NICNAS and the APMF was the priority existing chemicals review of lead compounds in industrial surface coating and inks. The APMF along with its industry members had embarked on a program to eliminate lead from those industrial surface coatings and inks where it continues to be used. The NICNAS assessment provided the basis for a regulatory framework to supplement this industry initiative[15].

Industry self-regulatory initiatives
The chemicals and plastics industry has a range of self-regulatory initiatives whereby the responsibility for management of risks arising from their use reside with industry. These initiatives have the support of the various Australian industry associations that provide support to their member companies. Examples include but are not limited to:

- The Responsible Care program – an international chemical industry initiative aimed at improving health, safety and environmental performance of its operations and to increase community involvement and awareness of the industry. The Responsible Care system consists of codes, guidance notes and checklists for implementation of good HSE practices.
- The Coatings Care initiative - developed as a health, safety and environmental initiative which also recognises the need to enhance product integrity and quality amongst paint manufacturers.
- ACCORD's Guideline for Cleaners and Sanitisers that may have incidental contact with food
- ACCORD's Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action developed to provide standards for advertising, labelling and performance to manufacturers and importers of cleaning products making claims of antibacterial action.

Conclusion
It is acknowledged that regulatory systems cannot operate only through primary and subordinate legislation alone. Such an approach does not recognise industry efforts to maintain their reputation and duty of care with respect to their products. The community expects higher standards of accountability from governments and public confidence in the regulatory system is paramount.

The challenge therefore, is to identify the correct balance between black letter law and co- and self- regulatory approaches that will deliver acceptable outcomes to all stakeholders. NICNAS has adopted the approach where any reduction in the scope and extent of pre- market assessment is balanced by post market compliance obligations.

5. Continuous improvement

With the introduction of full cost recovery for NICNAS assessment functions in 1997, it was recognised that that the assessment categories available at that time did not differentiate between hazardous chemicals and less hazardous (safer) chemicals. This prompted a number of innovations to encourage the introduction of safer chemicals into Australia.

Since that time NICNAS has been very responsive to stakeholder concerns and emerging issues and has moved to increase the efficiency and effectiveness of the regulatory system. These regulatory reforms were specifically aimed at promoting the introduction of safer chemicals, technological innovation, and a streamlined pathway to commercialisation onto the Australian market.

Uptake of individual reforms are presented in Table 1.

Reforms introduced between 1997 and 2003
Early reforms addressed industry concerns about the timeliness of assessment processes, the use of overseas assessment data and inflexible notification categories. These reforms provided efficiencies for industry through;

- reduced data requirements;
- reduced notification costs; and
- reduced time to market.

Benefits to the community included a greater number of low risk chemicals resulting in minimising the risk of environmental degradation and/or of adverse human health effects.

Specific reforms and their utilisation by industry

1. The introduction of a 10 kg per year exemption thresholds for new industrial chemicals within specified risk parameters, that is, the chemicals must pose no unreasonable risk to workers, the public or the environment (1997). This exemption has been used increasingly in particular by the cosmetics industry. This exemption threshold was increased in 2004 (see below).

2. Introduction of an Early Introduction Permit (EIP) (1997)- Companies introducing non-hazardous chemicals (human health criteria) that met specific environmental criteria could apply for early introduction of the chemical onto the market while the full assessment is undertaken by NICNAS. This reduced time to market from 90 days to 28 days. A sustained trend of uptake by industry has been observed with approximately one third of new chemical certificate applications accompanied by an EIP application.

3. Broadening of criteria for polymers of low concern (PLC) (2002) - this encouraged the introduction of non-hazardous polymers into Australia and aligned the scheme with the USA and Canada. There has been a sustained increase in the use of the PLC category since these reforms were introduced.

4. Amendments to the Commercial Evaluation Permit (CEP) category (2003) - increased the volume available under the CEP from two to four tonnes. This increase was balanced by requiring industry to provide a summary of the chemical's health and environmental effects at the end of the commercial trial and introduced user

agreements for persons who agree to be bound by the conditions of use under the CEP. A consistent level of utilisation was observed for CEP prior to the increase in volume, which was followed by a drop in the number of applications post 2003.

5. Introduction of Extension of the Original Assessment Certificate (1997) - enabled companies to utilise another company's pre-market assessment by NICNAS. The partner company is able to enter the market more quickly and at a reduced fee. The uptake of this assessment category has been variable over the years with approximately 100 extension certificates having been granted to date.

6. Introduction of electronic notification templates for certificate applications (2002)- Up to a 15% rebate on application fees was made available to industry using these templates. An increasing trend has been observed in the utilisation of the electronic templates since their introduction.

NICNAS Reforms introduced from 2004 to 2006

A key stimulus for these reforms was the Government's Response to the Chemicals and Plastics Action Agenda Steering Group Report, *Underpinning Australia's Industrial Growth, Report to Government*[7].

Activities under the Chemical and Plastics Action Agenda were undertaken by government and industry working in partnership to progress issues identified by industry to improve Australia's competitiveness and support the safe use of chemicals and plastics. In announcing the Government response to the Chemicals and Plastics Action Agenda report, the Government committed itself to, amongst other things, reducing unnecessary regulation and developing options for access to adequately assessed and/or tested chemicals presenting low regulatory concern.

The Low Regulatory Concern Chemical (LRCC) reforms introduced flexibility into the assessment process to enable the fast tracking of low regulatory concern chemicals while maintaining existing levels of worker safety, public health and environmental standards. The reforms also enabled the regulatory effort expended by the regulator and industry to be commensurate with the risk posed by these chemicals. The LRCC reforms have allowed the government to deliver benefits to industry while providing assurance that the reforms will lead to improved health, safety and environmental outcomes for all Australians.

Attachment 1 details individual reforms under the LRCC and their implementation status. Following is a summary of the main reforms under LRCC:

- Establishment of the NICNAS CEF. The CEF and NICNAS developed the NICNAS Community Engagement Charter, consisting of principles and protocols for effective engagement with stakeholders. The CEF was instrumental in the success of the stakeholder consultations for the review of the NICNAS Existing Chemicals Program.
- Introduction of NICNAS registration for all introducers of industrial chemicals to enable the Government to identify legitimate introducers of industrial chemicals, facilitate information provision and effective compliance with the Act.

- Introduction of low risk chemicals by broadening the range of exemptions from assessment, eg higher volume exemptions for low hazardous chemicals, cosmetics and chemicals for research and development and a special permit for chemicals for export only. These reforms are consistent with comparable overseas schemes and enable industry to be more competitive in the global marketplace.
- Introduction of audited self-assessment, where industry could submit assessments for polymers of low concern and low hazard chemicals using customised electronic templates, provided incentives for industry to introduce safer chemicals.
- Easier access to chemical safety information by updating the NICNAS website and publishing AICS on the website. The latter enabled notifiers to self-determine whether industrial chemicals required notification to NICNAS.
- Reduction of the compliance burden on industry by enabling the immediate listing of new chemicals on AICS and streamlining the renewal of permits.
- Clarification of the regulatory position for products at the cosmetic-therapeutic interface. This has aligned Australian regulatory requirements with major trading partners and streamlined the regulation of these chemicals while maintaining product safety standards.

A few outstanding LRCC reforms are currently being implemented. These changes will enable the further introduction of more low risk chemicals and greater acceptance of assessments conducted by other national and international assessment agencies.

For some reforms benefits are easily identified but difficult to quantify. Some of these are listed below.

1. AICS online - public access to the non-confidential AICS via the NICNAS website has resulted in time savings for industry and NICNAS. This is evidenced by a significant reduction in the AICS search requests received by NICNAS. In 2001-02 the number of AICS searches received was in the order of 2600 per year. This fell to approximately 400 chemical searches in 2004-05 when the inventory was made publicly available and a search fee was introduced for industry searches. NICNAS supports industry capacity to search the inventory through free AICS "self search" training.

2. Immediate AICS listing of new chemicals assessed by NICNAS. This enables greater access to assessed chemicals. In 2005-06, 51 chemicals were listed on the AICS immediately following assessment

Cosmetic reforms

During the LRCC reforms industry and government agreed that there was an urgent need to review and clarify regulatory requirements for lower risk products at the interface between therapeutics and cosmetics. NICNAS and the TGA in partnership with industry and the community developed the *NICNAS Cosmetic Guidelines*[16] which formed the basis for these reforms.

The *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007* came into effect in September 2007 and provides for the Minister to make standards, by legislative instrument, for cosmetic products imported into or

manufactured in Australia, and introduces penalties for non-compliance with these standards.

Table 1.Uptake of individual reforms

Applications received	**97-98**	**98-99**	**99-00**	**00-01**	**01-02**	**02-03**	**03-04**	**04-05**	**05-06**
Low volume exemptions [(1)]									
- cosmetic chemicals [(2)]	145	85	132	197	276	338	396	104	66
- non-cosmetic chemicals [(2)]	9	18	21	36	12	34	19	51	76
Early introduction permit	6	41	53	46	42	43	60	46	52
Commercial evaluation permit	55	52	38	51	33	43	20	26	51
Polymers of low concern	26	44	57	64	64	73	85	95	61
Audited self-assessment									
- polymers of low concern	N/A							45	45
- non hazardous chemicals and polymers								none	2

(1) Note: while notification of chemicals for cosmetic use was mandated, notification of chemicals introduced for non-cosmetic use was optional, therefore the figures for non-cosmetic use are expected to be an underestimate

(2) Note: some changes were introduced prior to the LRCC and further explored through the LRCC

pre reforms
post reforms

Source: NICNAS Annual Reports[17]

In order to allow industry access to the outcomes of the cosmetics reforms and pending legislative under pinning, the Director introduced interim arrangements in February 2006. Under interim arrangements six cosmetic product categories that met the *NICNAS Cosmetics Guidelines* were regulated as cosmetics based on a product-by-product agreement between the company and the Director NICNAS. These were antiperspirants, antidandruff products, primary sunscreens with SPF less than 4, moisturisers with secondary sunscreens (SPF $\geq$4 to $\leq$15), anti-acne skin cleansers and antibacterial skin products.

Approximately 300 interim permits were issued up to September 2007. NICNAS has undertaken a series of training sessions aimed at increasing awareness of the cosmetic reforms to facilitate industry compliance with revised requirements. These interim arrangements were subject to NICNAS audit.

Industry has advised that these reforms have afforded significant benefit to the sector. Benefits to the community include full ingredient disclosure for a greater range of personal care products and that new ingredients in these products will additionally be subject to worker and environmental risk assessments (previously only assessed for public health considerations).

Review of the Existing Chemicals Program

NICNAS has reviewed its Existing Chemicals Program through a need to meet the concerns and priorities of its stakeholders while ensuring an efficient and effective utilisation of resources. 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, in particular, noting that the majority of the approximately 38 000 existing chemicals available for use in Australia have not been adequately assessed for their risks to human health or the environment.

Hence the review considered ways of enhancing the efficiency and effectiveness of the program, its flexibility and responsiveness and included a comparison with similar international assessment programs in order to deliver best practice chemicals regulation.

The final report *Promoting safer chemical use: towards better regulation of chemicals in Australia – Final report and recommendations* was published in December 2006[18]. The report identified five key reform drivers, namely:

- better engagement and communication
- enhancing mechanisms to identify chemicals of concern: new screening processes
- improving efficiency
- targeted assessments, and
- increasing legislative reach: enhanced control powers.

The report contains 23 recommendations, expected to enhance regulatory efficiency and lead to more effective outcomes for the community, industry and government. They 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 proposed reforms are consistent with international trends towards best practice regulation for existing industrial chemicals. A number of the reforms are similar to those adopted by other international regulatory bodies and therefore present

opportunities for greater international cooperation and harmonisation on chemical safety issues.

These reforms will be implemented as an integrated package, which will ensure full community confidence in NICNAS and its existing chemicals program while enabling greater efficiency and effectiveness to flow on to all stakeholders. Those recommendations that can be directly implemented by NICNAS are already underway. An Implementation Steering Group comprising governments, industry and the community will provide strategic direction to the implementation of these recommendations.

Post 2006: Disinfectants

The Report of The Taskforce On Reducing Regulatory Burdens On Business: *Rethinking Regulation* (Banks Review)[8] recommended that the Australian Government progress industry reforms for regulating disinfectant products. In response the Government announced a review of the regulation of disinfectant products to be led by NICNAS and the TGA. This review is currently underway and progress will also be reported to COAG, as part of the ongoing reporting on the implementation of the recommendations from the Banks Review.

An independent review on current regulatory arrangements for disinfectants in Australia, examination of the regulation of disinfectants in other countries and presenting best practice options for streamlining the regulation of disinfectants will be released for public comments shortly. Currently all disinfectants are regulated by the TGA; the review presents options for low risk disinfectants used in domestic and commercial situations to be regulated by NICNAS. Consultation on these matters with industry, government and the community will be undertaken in 2007-08.

Response to emerging technologies: Nanotechnology

Nanotechnology represents a broad range of old and new technology platforms, with application across a number of industry sectors. Nanomaterials, when used as industrial chemicals, fall within the remit of NICNAS. NICNAS is engaging with the National Nanotechnology Strategy via a cross-portfolio working group on health, safety and environment issues, and is examining nanotechnology to determine if and how NICNAS needs to adapt its legislation and processes to ensure the safe and sustainable use of industrial chemicals that contain nanomaterials.

To this end, NICNAS is engaged in such activities as:

- Determining the volumes and types of nanomaterials that are being used within Australia as industrial chemicals;
- Influencing international developments in nanomaterials by active participation in the OECD Working Party on Manufactured Nanomaterials;
- Establishing a NICNAS Nanotechnology Advisory Group to advise on strategic directions NICNAS might take in addressing the potential impacts of nanomaterials as industrial chemicals;
- Determining if NICNAS legislation and associated regulations are adequate to managing any health, safety and environment challenges that nanomaterials might pose; and
- On-going reform of its chemicals programs to ensure they remain at the forefront of international best practice and are readily adaptable to emerging challenges in industrial chemicals regulation, including the challenge of nanotechnology.

Evaluation of major reform activities
It is NICNAS's policy to undertake evaluations of major reform activities to determine impacts on industry, the community and government (including the impact on NICNAS). In general evaluations are commenced following a reasonable period following implementation. An evaluation of the LRCC initiatives that are already in place is planned for 2007-08.

Conclusion
NICNAS continues to reform its programs in response to stakeholder concerns and emerging issues within the context of COAG principles and guidelines. Consistent with its Community Engagement Charter, all NICNAS reforms are undertaken in full consultation with the industry, community and various levels of government.

In the main, reforms implemented to date have afforded significant benefits to the chemicals and plastics industry while maintaining or enhancing health, safety and environmental standards. NICNAS reforms are benchmarked against international best practice and aim to harmonise regulatory requirements with major trading partners, where possible. Significant reforms have been made to the scheme since 1997 and a process of evaluation will enable NICNAS to identify issues that need to be considered when undertaking new reform activities.

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Attachment 1

LRCC reforms implementation status

No	Recommendation	Implemented	Currently being implemented
1 Audited self-assessment – legislative framework in place			
1.1	Establish process for audited self-assessment	✓	
1.2	Introduce permits for low hazard chemicals in low volumes		✓
1.3	Audit system in place for self-assessments	✓	
1.4	Electronic tools developed for self-assessments	✓	
2 Modular assessment			
2.1	Recognises assessment by another Australian regulatory authority	✓ (in part)	✓
	Substances of known hazard and controlled use		✓
	Modular assessments for analogues		✓
	Assessment by international authority or foreign scheme	✓	✓
	Low concern polymers not accepted for self-assessment	✓	
	Develop modular assessment fees		✓
3 Exemptions – legislative framework in place – including Record keeping and Annual Reporting formats			
3.1	Transhipment exemption	✓	
3.2	Introduce exemption for low hazardous >100kg	✓	
3.3	Non-hazardous chemicals in cosmetics at 1% or less	✓	
3.4	Increase R&D to 100kg/12 months	✓	
3.5	Increase low volumes for non cosmetics to 100kg/12 months/introducer	✓	
4 Polymer regulation – legislative framework in place			
4.1	Introduce legislative framework for audited self-assessment for PLCs	✓	
4.2	Low hazard permit for polymers in low volume		✓
4.3	Introduce audited self-assessment for low regulatory concern polymers		✓
5 Cosmetic chemicals regulation – legislative framework in place			
5.1	Self-assessment < 10kg	✓	
5.2	Notification only (not assessment) for low hazard 10 to100kg	✓	
5.3	Amend definition of cosmetic for national consistency	✓	
5.4	Products at cosmetic-therapeutics interface	✓	
6 Controlled use – legislative framework in place			
6.1	Introduce controlled use permits		✓
6.2	Introduce Export only permit	✓	
7 Incentives for the introduction of new and safer technologies – legislative framework in place			
7.1	Modular assessment		✓
7.2	Early introduction permit for low hazard and low risk chemicals – revise criteria		✓
7.3	Low hazardous permits for low volume		✓
8 International cooperation			
8.1	Bilateral with Canada (renewal)	✓	
9 Reducing the compliance burden – legislative framework in place			
9.1	Administrative permit renewals	✓	
9.2	Immediate AICS listing on request	✓	
9.3	Guidance for definition of naturally occurring substance		✓
10 Safe use through compliance – legislative framework in place			
10.1	Introduce mandatory NICNAS registration	✓	
10.2	Use of NICNAS registration number	✓	
10.3	Identify opportunities for co-regulatory activities	✓	
11 Access to chemical safety information – legislative framework in place			
11.1	Update website, including the AICS on the website	✓	
12 Community participation.			
12.1	Establish community consultative forum	✓	
12.2	Develop a Community Right to Know Charter	✓	
12.3	Develop a Community Engagement Strategy	✓	