DISCUSSION PAPER

REVIEW OF THE NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

JUNE 2012

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**ACRONYMS USED IN THIS DISCUSSION PAPER**

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<td>AICS</td>
<td>Australian Inventory of Chemical Substances (see Glossary, above)</td>
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<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority</td>
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<td>COAG</td>
<td>Council of Australian Governments</td>
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<td>DSEWPaC</td>
<td>Australian Government Department of Sustainability, Environment, Water, Population and Communities</td>
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<td>DEEWR</td>
<td>Australian Government Department of Education, Employment and Workplace Relations</td>
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<td>Australian Government Department of Health and Ageing</td>
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<td>EU</td>
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<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
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<td>ICNA Act</td>
<td><em>Industrial Chemicals (Notification and Assessment) Act 1989</em></td>
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<td>IMAP</td>
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<td>LRCC</td>
<td>Low Regulatory Concern Chemicals (NICNAS)</td>
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<td>MoU</td>
<td>Memorandum of Understanding</td>
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<td>NICNAS</td>
<td>National Industrial Chemicals Notification and Assessment Scheme</td>
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<td>PACIA</td>
<td>Plastics and Chemicals Industries Association</td>
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<td>PC</td>
<td>Productivity Commission</td>
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<td>PEC</td>
<td>Priority Existing Chemicals</td>
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<td>PLC</td>
<td>Polymers of Low Concern</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>US EPA</td>
<td>United States Environment Protection Authority</td>
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PART 1 – CONTEXT AND BACKGROUND

The chemicals industry in Australia

Chemicals are widely used in the Australian community with chemicals present in an extensive range of products including agricultural pesticides, household cleaners, cosmetics, petroleum and coal products and pharmaceutical products.

The chemicals industry directly employs over 53,000 people and represents between nine and ten percent of total Australian manufacturing activity\(^1\). According to the Plastics and Chemicals Industries Association (PACIA), the annual turnover in this industry sector is approximately $33.6 billion in Australia. In a global context, Australia represents approximately 0.6% of global sales of chemicals and about 0.85% of global trade in chemicals (source: PACIA). In 2010-11, a total of 4,759 businesses registered with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as manufacturers or importers of industrial chemicals in Australia.

Industrial chemicals have a diverse range of uses in society including as ingredients, additives, plastics, rubbers, solvents, foams and adhesives that appear in furniture, automotive components, paints, textiles, packaging, medical ware, cosmetics and building and construction products.

Given the diversity and reach of industrial chemicals in our society, and the associated risks to human health and the environment, there is a role for government intervention in the regulation of industrial chemicals. The focus of this Discussion Paper is the nature of that regulation and the potential to improve the efficiency and effectiveness of NICNAS.

Chemicals regulation in Australia

The Australian chemicals institutional and regulatory arrangements are complex, involving some 140 pieces of legislation and multiple policy departments, assessment agencies, and regulatory decision-makers at the Commonwealth and state and territory and local levels of government.

In general:

- the policy settings for government regulation of the chemicals industry are determined by ministerial councils
- the Commonwealth undertakes most hazard and risk assessment and implements international agreements

\(^1\) Department of Innovation, Industry, Science, Research and Tertiary Education.
• the states and territories typically focus on risk management and control of use. The regulatory regimes cover: public health; work health and safety; the transport of dangerous goods; disposal; and environment protection

• local government involvement varies considerably, but is usually limited to planning and waste disposal issues.

**Australian Government chemicals assessment and registration schemes**

There are four chemical assessment and registration schemes which are intended to operate in a complementary manner at the national level:

• industrial chemicals are notified to, and assessed by, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

• pesticides and veterinary medicines are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

• therapeutic goods are regulated by the Therapeutic Goods Administration (TGA)

• the use of chemicals in food and food additives is subject to standards set by Food Standards Australia New Zealand (FSANZ) and enforced under State/Territory food laws.

**National Industrial Chemical Notification and Assessment Scheme (NICNAS)**

NICNAS undertakes evidence-based assessments of risk to public health, occupation health and safety and the environment of certain industrial chemicals.

NICNAS assessments may result in the issuing of an assessment certificate or permit under the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) which allows the introduction of a new industrial chemical into Australia. In addition, a new chemical may also be introduced under one of the exemptions for low risk chemicals outlined in the ICNA Act.

NICNAS assessments certificates make risk management recommendations to Commonwealth, State, Territory and local government agencies. These risk managers are then responsible for considering NICNAS recommendations and determining any necessary risk management conditions to control the use, release and disposal of industrial chemicals.

NICNAS has some risk management responsibilities, implemented through post-market monitoring of exemptions, conditions under permits and conditions on AICS.
The current review of NICNAS

In September 2011, the Australian Government announced a review of NICNAS. The purpose of the review is to examine the role of NICNAS within the broader institutional and regulatory framework for chemicals regulation.

The NICNAS review is being undertaken as a Better Regulation Ministerial Partnership between the Minister for Finance and Deregulation and the Minister for Health. The Australian Government Department of Health and Ageing (DoHA) and the Department of Finance and Deregulation (DoFD) are undertaking the review to inform the Partnership.

The review will investigate how the regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes. The review will include, but is not limited to, assessing and making recommendations in relation to:

- the role and functions of NICNAS as set out in the ICNA Act and the extent to which they adequately reflect stakeholder expectations and international best practice, having regard to the broader context of chemicals regulation in Australia
- the governance and consultation arrangements of NICNAS and the extent to which they support the effective delivery of NICNAS’ functions
- the efficiency and effectiveness of NICNAS’ operating arrangements and business processes, with particular regard to the protection of human and environmental health, the management of risk, and compliance costs for business
- any implications for the resourcing of functions currently cost recovered, should the review recommend changed responsibilities.

The review will have particular regard to the recommendations of the Productivity Commission Research Report: Chemicals and Plastics Regulation, July 2008 and relevant commitments made, and reforms being progressed, under the Council of Australian Governments’ Seamless National Economy National Partnership Agreement, 2008.

As the review focuses specifically on NICNAS and the assessment and regulation of industrial chemicals, this review will not address the institutional and regulatory arrangements for chemicals more broadly.

Inputs into the review

To date the review has been informed by:

- submissions made by interested stakeholders. Between 1 November and 14 December 2011, written submissions were sought from stakeholders. A
total of 21 submissions were received. Submissions are available on the DoHA website at:

• an internal review of NICNAS’ arrangements, functions and processes which was undertaken to inform this Discussion Paper

• discussions with NICNAS and other Commonwealth agencies.
PART 2 – PURPOSE OF THIS DISCUSSION PAPER

The purpose of this Discussion Paper is to:

• provide an overview of the submissions made by stakeholders and the results of the internal review (Part 3)

• propose some possible options for reform (Parts 4 to 8)

• seek further input from stakeholders about the specific options for reform. In particular, to hear stakeholder views on the practical operation of the proposed reforms and the likely impacts including any costs or benefits to industry or other stakeholders should the reforms be adopted.

The intention is to use the views and ideas collected through consultation on this Discussion Paper to:

• further develop the detail of reform options which have been proposed

• prepare a Regulatory Impact Statement

The Discussion Paper has been structured in line with the main areas of reform identified by stakeholders, namely:

• the regulatory framework for industrial chemicals (Part 4)

• the assessment and management of new industrial chemicals (Part 5)

• the assessment and management of existing industrial chemicals (Part 6)

• post market monitoring and enforcement (Part 7)

• reforms that are applicable to both new and existing industrial chemicals such as reforms relating to the governance of NICNAS, the treatment of confidential commercial information and treaty responsibilities (Part 8).

In relation to each area of reform, the Discussion Paper describes:

• the current situation - given the complex nature of the current system for the regulation of industrial chemicals, some stakeholders have identified a lack of clarity about the role of NICNAS and the overall structure of the regulatory framework for chemicals. Before discussing possible reforms, it is therefore useful to summarise the existing situation

• the problem - stakeholder submissions provided a diverse range of views regarding the problem requiring action
• the objective sought to be achieved through reform

• the possible options for reform, noting that a number of the options are complementary and that more than one option may be appropriate to address a particular issue.

Following the description of possible reforms in each Part, a series of questions are asked. Feedback on these questions is sought from interested stakeholders. Further information about how to make a submission is included in Part 9.
PART 3 – SUMMARY OF STAKEHOLDER SUBMISSIONS AND OUTCOMES OF INTERNAL REVIEW

Stakeholder submissions

The regulatory framework for industrial chemicals (including the role of NICNAS)

On the whole, stakeholders agreed that the industrial chemicals regulatory framework is complex, and that a lack of clarity and fragmentation poses a challenge. Numerous examples were provided to demonstrate this point. For example, it was suggested that:

- while NICNAS operates alongside three other Australian Government regulators and the relationship between the agencies is intended to be complementary, in practice there are challenges to ensuring that roles and responsibilities are clear and that there is no duplication of effort

- there is a lack of clarity around responsibility for policy compared to regulation. Questions were raised as to who is responsible for issuing statements and advice in relation to government policy, interpretation of policy and risk communication

- regulatory interventions at both Commonwealth and state and territory levels leads to different regulatory outcomes and inefficiency for industry participants having to navigate through a large number of pieces of legislation

- the risk tolerance of NICNAS and the approaches to different risk-level applications could be improved, with more transparency and communication of the acceptable level of risk

- the fragmented regulatory system creates ‘gaps’ in regulation – particularly in relation to management of risks to environment, health and national security.

In some submissions it was suggested that an overarching body could be established to ensure that regulation across various agencies is consistent and sufficient to protect public health and safety, and safe use of chemicals in the work setting. This body would sit outside NICNAS but ensure that NICNAS, APVMA, FSANZ, TGA and the risk managers (for example, Safe Work Australia and the poisons scheduling area of DoHA) are consistent in their approach to chemicals assessment and management.

The issue which attracted the most comment was that of NICNAS’ role within the industrial chemicals framework. It is also an issue on which there was a diverse range of views.
On the one hand, some stakeholders suggested that:

- NICNAS’ role is too narrowly defined and there is little or no scope to ban or restrict the use of dangerous chemicals; to track and monitor use; and to respond to risks which emerge post-market

- there are current ‘gaps’ in the regulatory system such that there are circumstances in which chemicals can be introduced into Australia, without adequate conditions of use, because there is no clear risk manager or there is a delay in risk managers considering the NICNAS recommendations and imposing any necessary conditions for safe use

- NICNAS should have the power to impose conditions, restrict or ban chemicals.

On the other hand, some stakeholders suggested that NICNAS should undertake a risk assessment role only and should not have the power to impose conditions or otherwise restrict or ban the import or manufacture of industrial chemicals.

**NICNAS assessment of new industrial chemicals**

A number of issues were raised in relation to NICNAS’ assessment of new chemicals. Comments were made about:

- the complex assessment processes

- the fact that the various exemptions, permits and certificates are not easily understood by industry (noting that there are approximately 30 different notification categories)

- the misalignment in the risk posed by new chemicals within specific notification and assessment categories and the resources expended in undertaking the assessments

- the lack of international harmonisation. A number of stakeholders expressed concern about the duplication of assessment effort where chemicals have been subject to contemporary evaluations in jurisdictions such as Europe and North America. It was variously suggested that:

  - NICNAS should better align its regulatory processes with those of other countries
  - NICNAS should use information generated overseas, including regulatory assessments, to ensure more timely assessments
  - Australia could consider adopting a system more like the European Union REACH framework – which is a single legal model for the Registration, Evaluation, Authorisation and Restriction of Chemicals which has replaced over 40 separate EU laws
NICNAS should adopt lists of banned/restricted use chemicals in the EU, Canada, USA and UK to ensure that the Australian community is not exposed to such chemicals.

NICNAS should have the capacity to consider overseas assessments but should continue to be able to take into account unique Australian conditions and not be bound by the decision of a foreign government as to whether a chemical is safe for introduction in Australia.

- The lack of flexibility for NICNAS to deal with chemicals introduced in low concentrations, such as fuel additives.
- The limited ability of NICNAS to undertake urgent assessments or re-assessments in response to issues of immediate concern, such as product recalls.
- The potential ‘gaps’ in regulatory coverage when NICNAS makes recommendations to risk managers and there is no other relevant risk manager or a delay in consideration of the recommendations or imposition of risk management conditions.

**NICNAS assessment of existing industrial chemicals**

Many stakeholders expressed concern about the slow progress NICNAS has made in assessing the approximately 38,000 existing and unassessed chemicals on the Australian Inventory of Chemical Substances (AICS).

Following are some of the different observations made by stakeholders in relation to existing chemicals:

- A more effective system for prioritisation is required. It was, however, acknowledged that a new assessment and prioritisation framework is being introduced on 1 July 2012 which will enable the screening and assessment of 3,000 chemicals over 4 years.
- The Priority Existing Chemical (PEC) assessment process is rigid and cumbersome and does not provide for adequate flexibility to provide rapid assessment and response.
- There is a lack of data for NICNAS to identify appropriate priority existing chemicals and an inability to identify which of the 39,000 chemicals on AICS are not in use.

Some suggestions for addressing these problems included:

- Enabling NICNAS to accept international assessment outcomes from recognised countries. It was suggested that this would reduce the cost to industry and would enable NICNAS to focus its attention on those chemicals that have not already been assessed by other countries.
• providing government funding to enable NICNAS to expedite the assessment of existing chemicals.

NICNAS post-market monitoring and enforcement

A number of stakeholders commented on NICNAS’ inability to undertake comprehensive post-market monitoring and enforcement of compliance.

Some specific areas of concern included:

• NICNAS’ inability to track, use and gather data (resulting in a limited understanding of the longer term effects of chemicals in Australia)

• NICNAS’ lack of modern, graduated compliance tools to adequately address enforcement issues that arise

• the absence of any mandatory system of adverse reporting

• the regulator does not have the basic power to be able to ban chemicals that have been banned overseas or shown to be harmful to human health or the environment.

Specific issues

While most submissions focused on the systemic problems (for example the role of NICNAS, the lack of NICNAS powers to restrict use or ban, the lack of acceptance of international assessment outcomes etc), a number of submissions highlighted particular chemicals of concern or aspects of regulation which are problematic for certain classes of chemical.

For example, concerns were expressed about:

• the regulation of fuel additives (which has limited the choice of available fuel cargoes in short fuel market situations)

• the regulation of cosmetics (which covers formulated products delivered from overseas)

• the stringent criteria used to assess polymers assessed as Polymers of Low Concern (PLC) and Limiteds

• the regulatory cost of introducing new ‘green’ and sustainable chemicals has meant ongoing reliance on less environmentally-friendly chemicals.
Other issues impacting on NICNAS’ efficiency and effectiveness

Other issues identified by stakeholders included:

• Costs – although Government policy is for NICNAS’ activities to be funded through cost-recovery, some stakeholders also thought that NICNAS should receive some budget funding to enable it to expedite assessment of existing chemicals and to undertake important post-market monitoring.

It was also suggested that the high introduction costs for chemicals being assessed for use in Australia could: deter introduction of more modern, cost-effective chemical substitutes; inhibit the development of small Australian companies; and inhibit the introduction of safer chemicals.

• Confidentiality – It was suggested that implementation of risk management measures by risk managers is impossible when chemical names are able to be kept confidential under the ICNA Act if so requested by the introducer.

• Governance and stakeholder consultation – On the whole, stakeholders were pleased with the nature and extent of consultation. However, various suggestions were made for improving the Director of NICNAS’ access to strategic and technical advice.

Internal review of arrangements, processes and functions

The objective of the internal review was to identify how costs to business could be reduced by delivering efficiency and effectiveness improvements to NICNAS’ internal governance arrangements, operational functions and administrative processes, while maintaining the protection of human health and environmental outcomes.

While NICNAS has demonstrated strong organisational performance and effectiveness in some key areas (including the achievement of key performance indicators in annual reports, strong stakeholder engagement mechanisms and consultation processes, and committed staff) there are also areas for improvement.

To assist in comparing the areas for improvement that were identified through the internal review with those identified by stakeholders, the internal review issues have been grouped against the same headings as those used to group stakeholder comments above.

The regulatory framework for industrial chemicals (including the role of NICNAS)

Consistent with the comments made by stakeholders, the internal review also identified the complexity of the system as a significant shortcoming.
A range of possible reform options were identified including, for example, establishing legislative linkages between the various risk management bodies, creating a standing committee to bring together the relevant bodies, and addressing gaps in regulatory coverage through amendments to legislation to clarify roles and responsibilities.

**NICNAS assessment of new and existing chemicals**

The internal review highlighted:

- process inefficiencies in the risk assessment processes for both new and existing chemicals which stem from the prescriptive nature of the ICNA Act
- that NICNAS does not have sufficient scope or flexibility to respond to chemical assessments of varying risk and complexity in a timely or efficient manner
- the need to define a clear policy position on the use of international chemical assessment outcomes by NICNAS and the potential value of requesting NICNAS to prioritise the expansion of approved foreign schemes under the ICNA Act.

**NICNAS post-market monitoring and compliance**

Based on comparisons with other regulators NICNAS has inadequate compliance management resources and enforcement tools to effectively support its compliance strategy.

**Other issues impacting on NICNAS’ efficiency and effectiveness**

In relation to governance:

- the absence of a strategic advisory capability in the current governance structure
- improvements could be made to the provision of policy advice by DoHA and also the provision of corporate support services to NICNAS.
PART 4 – THE REGULATORY FRAMEWORK FOR INDUSTRIAL CHEMICALS

The current situation

As noted in Part 1 of this Discussion Paper:

- the overall chemicals framework in Australia comprises a variety of bodies performing functions (policy oversight, risk assessment, risk management and enforcement) across a number of sectors (work health and safety, public health, the environment, product safety, transport)

- NICNAS is one of four chemical assessment and registration schemes that operate in a complementary manner at the national level.

A key role of NICNAS is to undertake evidence-based assessments of certain chemicals and make risk management recommendations to Commonwealth, State, Territory and local government agencies. These other risk managers are then responsible for considering NICNAS recommendations and determining any necessary risk management conditions to control the use, release and disposal of industrial chemicals. This ensures that public health, worker safety and environmental risks can be managed as far as possible across the multiple sectors within the overall chemicals regulatory framework.

The areas of regulation (managed by other Commonwealth, state and territory bodies) include:

- public health through the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). The purpose of the Poisons Standard is to promote uniformity in the scheduling of substances and in labelling and packaging requirements across the States and Territories

- work health and safety. Safe Work Australia has the primary responsibility of improving work health and safety and workers’ compensation arrangements across Australia. Through Safe Work Australia, Commonwealth, state and territory legislation imposes a duty of care on employers to protect workers from the risks of hazardous chemicals

- consumer product safety issues. The Australian Competition and Consumer Commission (ACCC) has responsibility for the regulation of consumer goods, which are products for personal, domestic or household use. Under the Australian Consumer Law, the ACCC advises the Minister responsible for Competition Policy and Consumer Affairs who may ban or compel the recall of consumer goods that will, or may, cause injury to any person. The Minister may also make or declare a mandatory safety standard or a mandatory information standard for particular consumer goods. The ACCC and state and
territory consumer protection agencies share responsibility for monitoring compliance and enforcing these regulations.

- environmental management. Commonwealth, state and territory agencies monitor and manage industrial chemicals in the environment.\(^2\)

- the land transport of dangerous goods is regulated under state and territory legislation that reflects the Australian Dangerous Goods Code Road and Rail (the Code). The Code sets out consistent technical requirements for the land transport of dangerous goods across Australia.

In addition to the role it plays in risk assessment and recommendation, NICNAS also:

- directly regulates the use of certain industrial chemicals via a system of exemptions, permits and annotations on AICS. This is discussed in more detail in Part 5

- undertakes some monitoring of chemical use through review of annual reports for exemptions, notifications for permits, notifications for certificates, assessing existing chemicals on a priority basis and registration of chemical introducers

- undertakes compliance and enforcement activity related to registrations, exemptions, permit conditions and annotations on AICS

- makes risk assessment and safety information for industrial chemicals widely available

- gives effect to Australia’s obligations under international agreements

- establishes and enforces national standards for cosmetics imported into, or manufactured in Australia.

**The problem**

As noted by stakeholders, the problems with the existing system are:

- the system is fragmented and complex and stakeholders have difficulty understanding the linkages between the regulators and their respective responsibilities. Stakeholders have noted that there are approximately 5 Ministerial Councils and in excess of 36 different Commonwealth, state and territory agencies involved in policy setting, risk assessment or risk management in relation to industrial chemicals

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\(^2\) Note that the Productivity Commission (PC) recommended the development of a national approach to environmental management of chemicals, which is being progressed, through the Standing Committee on Environment and Water, in parallel with the review of NICNAS.
• there are gaps in regulatory coverage for industrial chemicals as well as areas of duplication (as identified in the PC Report and discussed further in Part 5 of this Discussion Paper)

• there is no common risk framework that applies across all of the agencies responsible for risk assessment and management in relation to industrial chemicals.

In addition, NICNAS has several MoUs and agreements with the relevant risk management agencies, a number of which are now outdated and not necessarily reflective of current roles and responsibilities. For example, a current MoU with State and Territories was signed in 1991 around the time that NICNAS was established.

The objectives of any reform

While continuing to operate within the existing multi-jurisdictional framework, the outcomes sought through this review are to:

• clarify the relative roles and responsibilities of the different agencies

• improve understanding of the regulatory system for industrial chemicals

• better describe the risk assessment and management framework within which NICNAS operates.

Possible options for reform

As noted in Part 1 of this Discussion Paper, this review is focussed on NICNAS and its role within the industrial chemical regulatory framework, rather than the broader framework for chemicals regulation generally. The review is therefore limited in terms of the recommendations that can be made in relation to the broader framework for chemicals regulation generally, and industrial chemicals specifically.

However, given the significant concerns expressed by stakeholders about the fragmentation and lack of clarity, it is important that this review considers proposals that relate to NICNAS but also have the potential to improve the system as a whole.

Following are some possible options for reform which could be implemented as a package, individually or as a combination of options.

A1. A detailed industrial chemicals risk assessment and management manual be developed. The manual would:

- describe the roles and responsibilities of each of the agencies involved in risk assessment and management of industrial chemicals
– describe NICNAS’ processes and approach to risk assessment and management
– explain how NICNAS’ processes and approach interact with other risk assessors and managers of industrial chemicals.

A2. Following the cessation of the Standing Committee on Chemicals, an ongoing Australian Government cross-portfolio group be established to consider chemical policy issues for the Australian Government. The group could for example: work to minimise duplication between Australian Government agencies; identify and develop options to address ‘gaps’ in regulatory coverage; and facilitate a co-ordinated approach to risk.

A3. Memoranda of Understanding (MOU) between NICNAS and other agencies (both Commonwealth and State and Territory) be reviewed and re-negotiated (or new ones developed) to ensure clarity regarding relative roles and responsibilities.

It should also be noted that many of the proposed reforms detailed in the following Parts are aimed at reducing duplication, closing gaps and improving clarity. To that end, they also contribute to the overall improvement of the regulatory framework for industrial chemicals.

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**Input sought from stakeholders**

Do you think that an industrial chemicals risk assessment and risk management manual would assist? If not, why not?

If so, what are the specific matters that could usefully be addressed in the manual?

What are the strengths and weaknesses of the options?

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3 The Standing Committee on Chemicals (SCOC) was established by the Council of Australian Governments under a Memorandum of Understanding to achieve an effective and efficient national system of chemicals and plastics regulation. The Memorandum of Understanding establishing SCOC expires on 7 December 2014. Further information on SCOC is available at [http://www.innovation.gov.au/INDUSTRY/CHEMICALSANDPLASTICS/SCOC/Pages/default.aspx](http://www.innovation.gov.au/INDUSTRY/CHEMICALSANDPLASTICS/SCOC/Pages/default.aspx)
PART 5 - NEW INDUSTRIAL CHEMICALS

The current situation

Currently under section 21 of the ICNA Act it is an offence to introduce (meaning import or manufacture) a new industrial chemical into Australia, except in the following circumstances (in which a person is permitted to introduce a new industrial chemical):

- if an exemption applies because the chemical poses no unreasonable risk (for example, because the chemical is introduced in very small volumes or subject to high levels of control or restricted access)
- if the introduction is in accordance with a permit (there are 5 different types of permits)
- the person holds an assessment certificate.

For new chemicals that are subject to an assessment certificate, introducers may also apply for early listing on AICS (after 5 years such chemicals are listed automatically). The effect of this is to define the chemical as an existing chemical and therefore enable anyone to introduce the chemical (within specified conditions of use, where applicable).

In general:

- the system of ‘exemptions’, ‘permits’ and ‘assessment certificates’ forms a regulatory hierarchy that aligns regulatory effort with risk
- **exemptions** apply to chemicals that meet the legislated criteria for an exemption. Such chemicals can be introduced under legislated exemption categories and do not require a certificate or permit. However, there are post-market obligations on the introducers of such chemicals to maintain records and submit annual reports to NICNAS. These obligations are enforceable and NICNAS can monitor compliance. In 2009-10, 6,974 chemicals were reported to be introduced through exemptions.
- **permits** are available for chemicals that meet the criteria. Again, these are relatively low risk chemicals and uses. As a result, applications for permits are subject to a streamlined, low-cost NICNAS assessment process. Following NICNAS assessment, a permit is issued to the introducer. The permit may be

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4 A new industrial chemical is defined in section 5 of the ICNA Act. In summary, a new industrial chemical is a chemical that is not listed on the Australian Inventory of Chemical Substances (AICS) or a chemical whose introduction is subject to a condition of use.

5 Please note that this is the number of chemicals reported to NICNAS under exemptions and does not take into account where several companies introduce the same chemical under exemptions.
subject to conditions of use and it is an offence not to comply with any conditions of use. The permit is time limited and may be renewed. Compliance with conditions of use is monitored and enforced by NICNAS. In 2010-11, 117 permits were issued by NICNAS

- **assessment certificates** are required for all new chemicals that do not meet the exemption or permit criteria. These chemicals are generally higher risk chemicals or uses. As a result the data requirements are generally more significant, and the NICNAS assessment process is more comprehensive.

Following an assessment, NICNAS issues a detailed assessment report which includes hazard identification, risk assessment and recommendations for regulatory controls and conditions of use. However, unlike for permits, NICNAS does not have the power to refuse an assessment certificate, nor does it have the power to impose conditions. Rather, the responsibility for imposing any regulatory controls or risk management conditions rests with relevant Commonwealth and State/Territory regulators. This might include, for example: public health regulators; Safe Work Australia; environment; transport; mining or other risk managers.

Following the issuance of an assessment certificate by NICNAS, the introducer is able to introduce the chemical into Australia (through import or manufacture) despite the fact that the risk management measures may not yet be in place. While some of the risk managers are able to apply risk management conditions relatively quickly (i.e. 8 weeks) others can take up to 2 years to consider the NICNAS recommendations, complete the necessary regulatory tasks and apply the risk management conditions.

Further, in some limited cases there are no relevant risk managers and so there are no means by which to consider whether conditions of use are required to manage risks and, if they are, to impose enforceable conditions. As a result, until such time as risk managers impose conditions of use, the system depends on the introducer voluntarily observing the recommendations made by NICNAS as part of the assessment.

For example, recently NICNAS considered a water purification chemical for home water filters. In this case, there was no clear risk manager so NICNAS made recommendations to the National Health and Medical Research Council (NHMRC) to consider including the recommendations in their drinking water guidelines. However, NHMRC is not a regulatory agency and as such the manner in which the guidelines will be enforced is unclear.

In 2010-11 NICNAS issued 165 certificates for new chemicals. Of these, NICNAS recommended that risk management measures be implemented by the risk managers for 56 chemicals

- **AICS** - For new chemicals that have been subject to an assessment certificate, the introducer may choose to apply to NICNAS to have the chemical listed on AICS. If the introducer does not apply to have the chemical listed on AICS it is...
automatically listed on AICS after 5 years. The effect of listing on AICS is that anyone can import or manufacture the chemical.

While NICNAS has a limited capacity to apply conditions of use on chemicals entered on AICS (also known as ‘annotation’), this power is seldom used. In most cases it would not be meaningful to apply a condition of use five years after the chemical has been in use (when there has been no capacity for NICNAS to apply a condition at the time of issuing the assessment certificate).

The problem

Risk assessment and risk management functions

As the PC Report noted, there are some advantages in separating risk assessment and risk management functions. As a result, the PC recommended that the power to annotate AICS (to include conditions of use) be removed along with any power to ban or phase out chemicals. The current power to annotate is not well described, transparent or logical in the regulatory system.

However, it would appear that there are also significant problems (as identified by stakeholders in submissions to the review and in the Australian Government’s response to the PC Report) with both the current approach and that proposed by PC.

While NICNAS is currently undertaking both a risk assessment and risk management function in relation to lower risk chemicals, for higher risk chemicals NICNAS loses the power to refuse an assessment certificate, to impose conditions of use or to monitor and enforce compliance (noting that other risk managers have responsibility for performing this role).

If, as suggested in the PC Report, NICNAS were to focus on hazard and risk assessment only, consideration may need to be given to NICNAS discontinuing its risk management, monitoring and enforcement responsibilities in relation to lower risk chemicals and uses (e.g. exemptions and permits). This approach was not supported by PC.

Alternately, consideration could be given to enabling NICNAS to perform a limited risk management/regulatory role (i.e. have capacity to refuse an application for a certificate, to impose conditions and to monitor and enforce) in relation to higher risk chemicals.

Complexity

The new chemicals notification framework is overly complex with more than 30 different categories for exemptions, permits and certificates. This is confusing for industry and leads to inefficiencies for both industry and NICNAS. A number of
these notification categories were introduced in 2004, as an outcome of the Low Regulatory Concern Chemical (LRCC) Reform Initiative, with the aim of improving flexibility. An industry evaluation\(^7\) of the first tranche of reforms, however, found that while the LRCC reforms were a ‘step in the right direction’ there was ‘great confusion within industry about the specific details of the LRCC provisions’.

**Other issues**

Other problems with the regulation of new industrial chemicals include the following:

- **exemptions** - Experience demonstrates that the list of exemptions has become outdated and unnecessarily restrictive. This was also raised as a concern by a number of stakeholders

- **permits** – the permit system can be confusing and overly restrictive in some cases, and as a result, under utilised.

- **assessment certificates** – The main issues in relation to assessment certificates are:
  
  - the certificate system can be confusing and overly complex for industry with over 20 different notification categories
  
  - the legislation does not enable NICNAS to reject an application that does not include the necessary information. Further, additional information can be submitted to NICNAS at anytime which is inefficient and delays the assessment process
  
  - NICNAS cannot refuse an assessment certificate which means that the chemical can be introduced despite posing unacceptable public health, worker safety and environmental risks
  
  - the risk managers may take time to impose conditions of use, resulting in a ‘gap’ in regulatory coverage during that period. There are also limited circumstances in which there is no appropriate risk manager and therefore no way to enforce the necessary condition of use in order to minimise risk to public health, worker safety and the environment

- **AICS** – The problems in relation to AICS are:

  - NICNAS cannot refuse to enter a chemical on AICS. This means that the chemical can continue to be introduced despite concerns that may have arisen following assessment surrounding unacceptable risk to public health, worker safety and the environment

NICNAS cannot effectively impose conditions of use on chemicals on AICS where there is either a regulatory gap and there is no relevant risk manager or the risk manager has not yet acted to impose the necessary condition of use.

Some stakeholders consider there is an additional problem shared by exemptions, permits and assessment certificates in that categories and data requirements do not adequately align with international regulatory systems. This adds regulatory burden for industry and administrative inefficiency for NICNAS.

The objectives of any reform

In addition to addressing the problems detailed above, consideration is being given to how NICNAS can achieve appropriate levels of health and environmental protection faster than it is currently able, noting:

• the importance of appropriate levels of protection for public health, worker safety and the environment

• enhancing competition and innovation in the industrial chemicals industry by removing unnecessary regulation and minimising the cost of regulation to industry

• the desirability of addressing ‘regulatory gaps’ where those gaps:
  – have the potential to pose risk to public health, worker safety or the environment
  – undermine consumer confidence in the regulatory system
  – present regulatory uncertainty for industry

• the need for clarity, certainty and transparency for industry, consumers and NICNAS

• the need to preserve and not disrupt the important role of risk managers, noting the complexity of the regulatory system for chemicals

• the importance of ensuring minimal duplication

• ensuring an appropriate risk continuum, with regulatory effort (both pre- and post-market) matched to risk.

Possible options for reform

As noted in Part 3 of this Discussion Paper, numerous suggestions were made by stakeholders about improvements that could be made to the system.
The anomalies identified above were highlighted by stakeholders and the proposed solutions varied enormously. Stakeholders also noted the desirability of being provided with clear options for consideration and comment.

The purpose of this Part of the Discussion Paper is to describe possible options for addressing the issues detailed above.

Please note that this section only applies to new industrial chemicals. Existing chemicals are addressed in Part 6, post-market monitoring and enforcement is addressed in Part 7 and Part 8 deals with other reforms that impact both new and existing chemicals.

Some possible options for reform for new chemicals follow. The options below could be implemented as a package, individually or as a combination of options (note that B4 and B5 are complementary). Please note that each of the options would be likely to result in changes to the ICNA legislation (either the Act or the Regulations) as well as administrative documents.

**B1.** In relation to all notification and assessment categories (for exemptions, permits and certificates):

- reduce the number of categories

- review current volume thresholds, data requirements and applicability criteria with a view to harmonising these with overseas arrangements where possible. The objective of this would be to better clarify and harmonise data requirements and reduce complexity for industry.

**B2.** In relation specifically to exemptions:

- consider new or expanded exemptions (e.g. options described in the LRCC evaluation report on increasing the volume limits and extending the 1% concentration exemption for non-hazardous chemicals in products).

**B3.** In relation to permits and assessment certificates:

- introduce a pre-assessment statutory screening process, with timeframes, to enable NICNAS to refuse an application if it does not include all the necessary information. Additional information would only be able to be provided following a request from NICNAS or under the legislative obligations to provide new relevant information (note the PC Report – recommendation 4.5).

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8 Option F1 also explores the use of foreign schemes and international assessments (Refer Part 8 of this Discussion paper).

9 LRCC Reforms: An evaluation of the impact on industry Final Report, June 2009
B4. In addition, in relation specifically to assessment certificates:

- streamline the assessment process (note the PC Report – recommendation 4.1). For example, a model operating in the US EPA involves four distinct successive technical phases: chemistry review, hazard evaluation, exposure evaluation and the risk assessment/risk management phase. These phases are structured to ‘drop’ (from further assessment) chemicals of low risk early in the review enabling resources to focus on higher risk chemicals. As an example, polymers which meet select criteria are commonly dropped during the chemistry review. Such an approach could be considered for the assessment of new chemicals.

- enable NICNAS to refuse an assessment certificate in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable level. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms.

- enable NICNAS to impose conditions of use on an assessment certificate where such conditions must be removed/lifted once NICNAS receives notification from the relevant risk manager that they have implemented measures that the risk manager has determined are necessary to manage the risk. Any conditions of use imposed by NICNAS would only extend to the introducer (importer or manufacturer) as is the case with permits. Further, NICNAS would not impose conditions which are general obligations under, for example, work health and safety law. Conditions would only be imposed where a control is necessary beyond a generic obligation. For example, where a concentration limit is necessary.

B5. In relation to AICS:

- provide that after five years, or if the holder of an assessment certificate applies to NICNAS to have the chemical entered on AICS (to enable its introduction by anyone), require that if the chemical is subject to conditions of use (because risk management measures have not yet been imposed by the relevant risk manager) that either: the chemical not be entered on AICS until these measures are in place; or these conditions also carry over to AICS. As for assessment

\[10\] An alternative to this approach is to delay the issue of an assessment certificate (or delay the date of effect) until such time as the relevant risk managers have notified NICNAS that appropriate risk management strategies/conditions of use are in place. This option was not supported by the PC (refer page 70 of PC Report).

\[11\] On the basis of a preliminary examination of past assessment certificates it is estimated that approximately 10% of assessment certificates would include recommendations that require controls that go beyond general legal obligations.
certificates, the conditions on AICS would be removed once other risk managers have ‘filled the gap’ (note the PC Report – recommendation 4.4)

- enable NICNAS to refuse to enter a chemical on AICS in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable limit. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms

- provide that if, during the 5 years following assessment of a new chemical, the introducer decides (for commercial reasons) to stop introducing the chemical, NICNAS may choose not to enter the chemical on AICS provided this occurs with the agreement of the company.

B6. Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicant’s appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

The possible advantages and disadvantages of the model described above are:

- it improves efficiency by expanding exemptions, introducing screening of applications for permits and certificates and adopting a streamlined modular assessment process for certificates

- it improves consistency with international approaches by better aligning exemption, permit and certificate categories with international models and also by introducing a modular assessment process

- it enables regulatory gaps to be filled without usurping the role of existing risk managers

- it may create some uncertainty for industry if the conditions of use imposed by NICNAS (on the assessment certificate) are not consistent with the measures subsequently imposed by the relevant risk manager. However, to the extent that industry is currently expected to follow NICNAS recommendations, this problem already exists

- at present NICNAS adopts a relatively conservative approach to pre-market assessment. This is, in part, because this is the only point of control for new chemicals. Whereas if there is capacity to ensure that necessary post-market obligations and conditions are in place, NICNAS’ pre-market risk tolerance
could increase, within the policy framework. This could potentially mean that the time within which products are brought to market could be reduced.

**Input sought from stakeholders**

What are the strengths and weaknesses of the options for addressing the problems and objectives identified?

If weaknesses are identified in relation to any of the options, are there other options that also meet the objectives?

If these options were to be adopted, what are some of the implementation issues that would require consideration?

What would be the likely impact on your organisation, if this approach were adopted?

If NICNAS were able to refuse both an assessment certificate (Option B4) or listing on AICS (Option B5), under what circumstances would this be appropriate?
PART 6 – EXISTING INDUSTRIAL CHEMICALS

The current situation

There are currently approximately 39,000 existing chemicals listed on AICS. Many of these were ‘grandfathered’ onto AICS and have not yet been assessed by NICNAS.

Until recently NICNAS predominantly used the process described in the ICNA Act (described below) to assess existing industrial chemicals. This Priority Existing Chemicals (PECS) process is limited and rigid.

In response to concerns regarding the need to accelerate and prioritise the assessment process for existing chemicals, NICNAS developed a science and risk based framework for the assessment and prioritisation of chemicals on the AICS (in consultation with stakeholders and technical experts). This is known as the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

From July 2012 existing chemicals assessments will predominantly be undertaken using IMAP.

The IMAP approach better enables appropriate assessment and prioritisation of existing chemicals.

The problem

Problems with the assessment process for existing chemicals include the following:

- the ICNA Act describes a detailed legislative assessment process for the assessment of Priority Existing Chemicals (PECs). While such a process may be appropriate for chemicals of national significance, the full PEC process is not appropriate for all assessments of existing chemicals. As noted by a number of stakeholders, the existing chemicals assessment processes is unnecessarily detailed and cumbersome for many chemicals. Although NICNAS can adopt non-legislative assessment processes to increase flexibility, this lacks regulatory certainty for NICNAS and stakeholders.

- the information-gathering and sharing powers in the Act are very limited and do not adequately enable NICNAS to request and obtain information in relation to existing chemicals. For example, the circumstances under which NICNAS can mandatorily call for information on uses, volumes and effects of existing chemicals are highly prescriptive. This limits NICNAS’ ability to undertake risk assessments and often results in the use of conservative default assumptions in the absence of accurate use and volume information.
• if NICNAS identifies serious concerns as part of the assessment of an existing chemical, the capacity of NICNAS to impose conditions on the use of the chemical (to manage any significant risks) is unclear. NICNAS does not have the power to remove the chemical from AICS. In such circumstances, the regulatory safeguards for the introducer are also uncertain.

• underutilisation of international assessments. Some stakeholders suggested that NICNAS should adopt assessments and/or assessment outcomes from the EU, USA, Japan, New Zealand and Canada rather than duplicating assessments. Other stakeholders strongly disagreed with this suggestion and supported independent assessment by NICNAS taking into account unique Australian conditions.

• no capacity to identify those chemicals that are no longer being introduced but are still on AICS. Regulatory effort is therefore potentially wasted in considering these chemicals as part of the existing chemical review. This has potential to impose unnecessary costs on industry.

The objectives of reform

In addition to the objectives identified in relation to new industrial chemicals, the objectives of any reform of the regulation of existing chemicals are to:

• streamline the assessment process, where possible, to ensure that the assessment approach is commensurate with the risk and is directed towards the most efficient management of the aggregate risk of all industrial chemicals (note the PC Report – recommendation 4.1)

• ensure transparency in any decision-making processes in relation to existing chemicals

• enable stakeholders to participate in the assessment process through, for example, opportunity to comment on the assessment report and its conclusions and recommendations

• ensure that NICNAS has access to adequate information to enable it to properly conduct risk assessments in relation to existing chemicals.

Possible options for reform

The options below could be implemented as a package, individually or as a combination of options (note that C3 and C5 are complementary). Some possible options are to amend the ICNA Act to:

C1. Maintain the existing assessment process for PECs but remove unnecessary prescriptive detail (including, for example, the requirement for both a preliminary assessment and a full assessment).
C2. Introduce a new legislative assessment process for non-PECs. Assessment outcomes would be published to ensure transparency but the assessment process would be simplified, could be carried out in relation to more than one chemical at the same time (e.g. assessment of a group or class of similar chemicals) and assessments could be more focused. For example, assessments could focus on a particular health effect or use pattern.

C3. Broaden the mandatory information-gathering powers to enable NICNAS to better undertake risk assessment activities and to adequately manage AICS (for example, to enable NICNAS to seek information from industry in support of option C5). The circumstances under which NICNAS may request such information would need to be tightly defined and be proportional to the risk. Care would also need to be taken to ensure that introducers are not required to submit the same information to multiple regulatory bodies.

C4. Remove the general power for NICNAS to impose conditions of use on chemicals after a chemical has been entered on AICS. This would be replaced with a much more limited power which would enable NICNAS to:

- impose a condition of use on a chemical listed on AICS only if an assessment of an existing chemical has been undertaken and the assessment has demonstrated that a condition of use is necessary, in order to protect public health, worker safety and the environment, and that there is no other means by which the risk can be addressed

- remove a chemical from AICS if NICNAS considers that there is unacceptable public health, worker safety or environmental risks, and risk management strategies are inadequate to manage the risk to an acceptable limit. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms.

C5. Establish a new Part on AICS for chemicals that are no longer being introduced into Australia. It is proposed that NICNAS would seek information from industry regarding those chemicals that have been introduced into Australia over the previous 5 years. Those chemicals that are on AICS but have not been introduced by any manufacturer or importer over the last 5 years would be placed on a separate list within AICS. If, after a further 5 years, no-one introduces the chemical the

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12 Currently NICNAS has the power to add a chemical to AICS and impose conditions if responsibility for the regulation of the chemical has been transferred from another Commonwealth regulator such as the TGA or APVMA (refer section 15AA and 15AB of the ICNA Act). If Option C4 were adopted, it is proposed that the power to add such chemicals to AICS (and impose necessary conditions) would be retained.
chemical would be removed from AICS following public notification and opportunity to comment.

**C6.** Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicants’ appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

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<th>Input sought from stakeholders</th>
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<tr>
<td>Do these options address the problems identified in relation to existing chemicals? If not, why not?</td>
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<tr>
<td>What are the implementation implications?</td>
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<td>If these options were (or were not) to be adopted, how would this impact on your organisation?</td>
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PART 7 – POST MARKET MONITORING AND ENFORCEMENT

The current situation

For chemicals that have been previously assessed by NICNAS, the ICNA Act imposes certain post-market obligations on introducers. For example:

- introducers are required to notify significant changes in circumstances of the use of an assessed chemical and any adverse health and environment impacts (known as secondary notification)

- NICNAS has the power to require annual reports on adverse effects and/or volumes for chemicals introduced under NICNAS exemptions and permits and certain self-assessment certificates.

However, most of the 39,000 chemicals on AICS have not been assessed by NICNAS for their health and environmental impacts. This means that the post-market obligations described above, do not apply in these circumstances and there is no legal mechanism for NICNAS to be advised of adverse effects arising from their use.

In terms of NICNAS’ overall efforts in relation to monitoring and enforcement activity:

- the primary focus of NICNAS’ compliance and enforcement program is administering the company registration process which accounts for approximately 60% of compliance program resources

- in 2010-11 NICNAS also undertook 126 site visits, conducted 642 desk audits and opened 40 new compliance cases. Compliance activities included action on reports of restricted ingredients in cosmetics, use of exemptions for chemicals that do not meet the exemption criteria, and companies not meeting registration requirements. Investigations led to eight new companies being registered, notification of three new chemicals and one company ceasing introduction of a chemical.

The problem

Four main problems exist in relation to post-market monitoring and enforcement:

- for those chemicals that have been assessed and are subject to secondary notification requirements, there are two main problems:
– the circumstances in which secondary notification is required are not clear. This is because currently AICS does not list the function or use of the chemical that was subject to the original assessment by NICNAS (nor is the assessment report linked to the AICS entry). This means that it can be difficult for introducers to know whether secondary notification obligations apply to them

– the assessment process (following secondary notification) can be unnecessarily cumbersome

• for those chemicals that have not been assessed by NICNAS, there is no effective system of adverse effects reporting as there are limited secondary notification requirements

• NICNAS lacks a modern graduated compliance regime, as compared to those utilised by other regulators. In many cases, the current legislation provides no intermediate step between the extremes of warning letters or minor fines and imprisonment.

The objectives of any reform

The objectives in relation to post-market monitoring and enforcement are to:

• ensure that NICNAS has access to adequate post-market information to enable it to properly conduct risk assessments in relation to existing chemicals. This must be balanced with the need to ensure that unnecessary and costly reporting obligations are not imposed on industry

• ensure that NICNAS has the necessary tools to properly perform its monitoring and enforcement responsibilities. If NICNAS continues to have a regulatory role then it is appropriate for NICNAS to have a comprehensive, graduated and contemporary compliance regime. This aims to enable NICNAS to better manage compliance by tailoring penalty provisions to the degree and seriousness of the non-compliance. It also has the potential to facilitate a level playing field for introducers.

Possible options for reform

The options below could be implemented as a package, individually or as a combination of options.

D1. Streamline the secondary notification process for existing chemicals. Consistent with the possible changes described at C2, the ICNA Act could be amended such that:

• NICNAS re-assessment following secondary notification could either occur using a streamlined approach or through the more comprehensive PEC-style approach, depending on the nature of the hazards and risks
- AICS could list the function or use of the chemical related to the original assessment. This gives clarity to the existing secondary notification obligations for significant variations to use.

**D2.** Supplement existing secondary notification requirements with a more comprehensive system of adverse effects reporting for new and existing industrial chemicals. Such a system would require introducers to mandatorily report adverse effects but would also enable anyone else, including users and risk managers, to report adverse effects to NICNAS. This could be similar to the APVMA system for adverse experience reporting.

**D3.** Introduce into the ICNA Act a comprehensive, graduated and contemporary compliance regime to enable NICNAS to better manage compliance by tailoring penalty provisions to the degree and seriousness of the non-compliance. For example, consideration could be given to the introduction of compliance tools such as assisted resolution, infringement notices and civil penalties.

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<td>Does an adverse effects reporting system address the problems and objectives identified?</td>
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<td>What would be the impact of an adverse effects reporting system on introducers?</td>
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<td>Are there other ways in which NICNAS' post-market monitoring and enforcement capacity could be improved?</td>
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PART 8 – OTHER REFORMS AFFECTING BOTH NEW AND EXISTING CHEMICALS

This Part of the Discussion Paper details those areas of concern, and options for potential reform, which are common to both new and existing chemicals.

Release of information and confidential commercial information

Currently under the ICNA Act an introducer can request that certain information be kept commercial in confidence. This can include, for example, the name of the chemical, its function and structure.

The capacity to protect confidential commercial information is an important part of the regulatory scheme that should be retained. However, there are circumstances in which the protection of such information compromises the capacity of regulators to perform their functions and for introducers to understand their obligations.

For example, currently NICNAS does not release information obtained for the purposes of the ICNA Act (including confidential commercial information) to other risk managers, such as information relating to individual companies. This adversely impacts the capacity of risk managers to implement risk management measures or to monitor compliance with existing regulatory requirements (such as labelling requirements under work health and safety legislation). This problem is compounded where the name of the chemical is also subject to confidentiality.

Further, if option D1 where adopted, then it would seem logical that the name of the chemical be known, as far as possible, such that the function and use related to the original assessment can be determined (particularly as at the time of listing a chemical on AICS anyone can introduce the chemical). A more limited form of confidentiality could be made available, aligning with contemporary provisions overseas (e.g. EU) and domestic legislation (e.g. work health and safety legislation).

Possible option(s) for reform:

**E1.** Amend the ICNA Act to enable release of information (including confidential commercial information) to other Commonwealth and state and territory agencies where it is necessary for them to fulfil their regulatory responsibilities. For example: to undertake an assessment of risk, to consider risk management strategies in relation to industrial chemicals or to monitor compliance with regulatory requirements.

**E2.** Amend the ICNA Act such that at the time of listing on AICS, the chemical name would be subject to contemporary confidentiality criteria to increase transparency (e.g. align with work health and safety confidentiality arrangements relating to chemical name).
Input sought from stakeholders

How would the release of information to other relevant government agencies impact introducers?

What are some of the implementation issues that would require consideration?

What would be the impact of these options?

Are there any other ways in which the identified problems can be addressed?

Use of foreign schemes/international assessments

Currently NICNAS supports international harmonisation initiatives and strategies to enhance the use of international assessments. NICNAS regularly participates (along with other Commonwealth agencies) in international chemical forums such as the OECD chemicals program and has formal Bilateral Arrangements with counterparts in Canada, the European Union, New Zealand and the United States.

Further, NICNAS currently uses international chemical assessments wherever possible (for example, as part of NICNAS' consideration of assessment certificates). This is expected to be enhanced as more assessments become available from other international chemical assessment schemes, for example, the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

In relation to the current situation, some stakeholders have suggested that:

- NICNAS' failure to accept assessment outcomes from other comparable regulators stifles innovation and limits the availability of chemicals in Australia

- there could be significant cost savings (and improved efficiency) if NICNAS were to accept approvals from other countries.

By contrast, other stakeholders suggested that NICNAS must retain the capacity to review assessments from other countries, noting differing risk appetites in different countries and different public health and environmental considerations.

The automatic acceptance in Australia of overseas approvals or refusals for new chemicals (i.e. mutual recognition of regulatory decisions) has a number of practical barriers including:

- the level of risk acceptable to the general population varies from country to country
• Exposure to humans and the environment varies depending on the use pattern of the chemicals

• Environmental considerations and population distributions vary between countries

• Checks and balances built into individual regulatory frameworks vary and need to be considered on a case-by-case basis when considering the appropriateness of accepting regulatory decisions from other jurisdictions.

Having said this, improvements could be made to the way in which overseas assessments are utilised and to facilitate international work sharing.

For example, in addition to Options B1-B6, possible options for reform include:

F1. Increase utilisation of international assessments to support and streamline the assessment for permits (noting that chemicals subject to permits are lower risk because there are ongoing post-market conditions and controls and there is a narrower set of uses)\(^\text{13}\).

F2. Better align the categories of, and data requirements for, exemptions, permits and certificates with, for example, the US, Canada and the EU\(^\text{14}\).

### Input sought from stakeholders

Do these options strike an appropriate balance between the use of international assessments/harmonisation and the need to ensure that Australia retains the capacity to undertake Australian relevant risk assessment and management where necessary?

If these options were to be adopted, what are the implications?

If these options were (or were not) adopted, how would this impact on your organisation?

### Chemicals in articles

The role of NICNAS in the regulation of chemicals that are in articles or products has been the subject of some confusion and some stakeholders have suggested that NICNAS should be able to directly regulate articles or products containing industrial chemicals.

Currently the ICNA Act expressly provides that an industrial chemical means a chemical that has an industrial use. A chemical is further defined so as to

\(^\text{13}\) This also has linkages with Option B4, streamlining the assessment process for certificates.

\(^\text{14}\) This is also discussed in relation to Option B1.
expressly exclude articles. An article is also defined in the ICNA Act yet this
definition is somewhat narrower than the generally understood definition of a
product.

The practical effect of this is that NICNAS does not regulate articles per se.
However, there has been confusion surrounding the extent to which NICNAS can,
or should, assess the risk from a chemical leaching/escaping from an article as
part of its assessment of the chemical.

It is not proposed that NICNAS commence regulation of all articles or products
containing industrial chemicals due to practical limitations. Aside from the
potentially large volume of products, NICNAS regulation of all products would
give rise to considerable duplication and overlap with other product regulators
including the ACCC and with the new product stewardship legislation.¹⁵

However, it is acknowledged that, there is value in clarifying the role of NICNAS
in relation to industrial chemicals in articles. Consistent with recommendation
5.4 of the PC Report, there is also value in clarifying relationships and
formalising arrangements between NICNAS and, in particular, the ACCC. Any
description of relative roles and responsibilities should also clarify NICNAS’
ongoing role in the assessment of the risks from chemicals leaching or escaping
from articles over the full life cycle of the article.

Possible options for reform:

**G1.** Clarify the role of NICNAS in relation to chemicals in articles as part of the
development of the industrial chemicals risk assessment and
management manual (option A1) and through the re-negotiation of MOUs
where necessary (option A3).

**G2.** Amend the ICNA Act to clarify the role of NICNAS in the assessment of
chemicals in articles, particularly imported articles.

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<td>Do these options address the problems relating to articles?</td>
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**Chemicals in cosmetics**

There are two aspects to NICNAS’ regulation of cosmetics. Firstly, NICNAS
assesses chemicals and a function or use of a chemical may be as an ingredient in
cosmetics. Secondly, NICNAS administers and enforces the Cosmetics Standard
2007 which sets out the ‘rules’ or ‘conditions’ that apply to certain cosmetic
product categories (currently six product categories) in order for them to meet
the definition of a cosmetic and therefore be regulated by NICNAS.

¹⁵The Product Stewardship Act 2011 came into effect on 8 August 2011. This legislation provides the framework to
effectively manage the environmental, health and safety impacts of products, and in particular those impacts associated
with the disposal of products.
Cosmetics must be labelled in accordance with the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991, that sets out the standards, the responsibilities of suppliers and retailers, and the ACCC’s role in enforcing cosmetic and toiletries ingredients labelling.

**Portfolio responsibility for Cosmetics Standard 2007**

The PC Report recommended that responsibility for administration and enforcement of the *Cosmetics Standard 2007* be transferred to the ACCC (recommendations 4.3 and 5.5 of the PC Report). The PC considered that:

- the responsibility for regulating products should be vested in a dedicated standard-setting body such as the ACCC, rather than a chemical assessment agency

- NICNAS should retain the responsibility for assessing new chemicals in cosmetics and also provide expert support to the ACCC in monitoring and enforcement of compliance with the Standard and in updating the Standard.

There are advantages and disadvantages to moving responsibility for the Cosmetics Standard. The main advantage of moving it to the ACCC is that it provides policy logic by ensuring that responsibility for the Standard rests with a standard-setting body.

By contrast, if the Cosmetics Standard were to be kept within the remit of NICNAS, this would ensure regulatory continuity and minimise duplication (noting that if responsibility is shifted to the ACCC, NICNAS would still need to provide technical advice to the ACCC in relation to the Standard).

**Regulatory approach to chemicals in cosmetics**

It is also acknowledged that the regulatory approach to chemicals in cosmetics requires re-consideration and reform.

Cosmetics chemicals involve different considerations to other industrial chemicals because they are widely used by the whole community and are generally used without additional protective measures (such as gloves or masks).

It may therefore be appropriate to introduce new provisions in the ICNA Act (and on AICS) specifically dealing with cosmetics. These could be based on the EU model and could include, for example, a separate inventory of cosmetic ingredients, positive and negative lists that provide more certainty for industry and a separate list of data requirements for the assessment of cosmetics chemicals.
Possible options for reform

**H1.** Responsibility for administration and enforcement of the *Cosmetics Standard 2007* be transferred to the ACCC but the assessment of chemicals in cosmetics would remain with NICNAS.

**H2.** New provisions could be introduced into the ICNA Act (and on AICS) to specifically deal with chemicals in cosmetics (rather than continuing to treat them like industrial chemicals). This could include a separate inventory of cosmetic ingredients, a list of ‘pre-approved’ cosmetic ingredients, a list of ingredients that are not to be utilised (based on risk), and a separate list of data requirements for the assessment of cosmetics chemicals. Better alignment with international approaches would also be explored.

### Input sought from stakeholders

If these options were (or were not) to be adopted, how would this impact on your organisation?

**Import and export of chemicals under the Stockholm and Rotterdam Conventions**

Currently, regulations under the ICNA Act are used to prohibit or restrict the introduction or export of industrial chemicals to give effect to some components of Australia’s obligations under two international agreements: the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in international trade (the Rotterdam Convention) and the Stockholm Convention on Persistent Organic Pollutants (the Stockholm Convention).

The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) has the lead responsibility for both these Conventions. The department is responsible for negotiating Australia’s position internationally and for conducting the National Interest Analysis and Regulation Impact Statement, which forms the basis for Australia determining whether to agree to ratify the listing of a chemical on either Convention. A decision to ratify commits Australia to meet the obligations imposed by the Convention on the management of the chemical.

Under the Rotterdam Convention, which deals with trade in hazardous chemicals, the principal obligation is that listed chemicals are subject to a prior informed consent procedure which requires Parties to the Convention to ensure that countries receiving exports of the chemical have provided their informed consent to receive such chemicals. Parties are not required to ban or restrict use or manufacture of listed chemicals.

Responsibilities under the Stockholm Convention, which can eliminate or severely restrict the use of a chemical, are significant and multi-faceted. They
include conditions on the import or export of the chemical but also can have major consequences for product stewardship and the management of wastes, stockpiles, and contaminated sites which are the responsibility of environment agencies and dealt with under their legislation and policies.

The PC report was not clear on these responsibilities. It acknowledged a role for NICNAS in administering the Stockholm Convention (because the PC thought it related primarily to chemical assessment, which is only one aspect of the responsibilities under the Convention) but suggested that the responsibility for those aspects of implementation of the Rotterdam Convention incorporated in the ICNA Act could be transferred to DSEWPaC (recommendation 4.3).

On the one hand, there is a case for consolidating the import and export responsibilities for the Stockholm and Rotterdam listed chemicals with the overall policy and management functions for the international chemical treaties, all of which reside primarily with DSEWPaC. A transfer to DSEWPaC could potentially achieve a more integrated approach to meeting Australia’s obligations under the two Conventions. This is the approach that was taken for ozone depleting chemicals and synthetic greenhouse gas chemicals which are the subject of international treaties and are dealt with comprehensively, including import and export, under legislation administered by DSEWPaC.

On the other hand, if an industrial chemical were subject to import and export controls under the ICNA Act regulations through domestic action before it were considered and listed under the Rotterdam and Stockholm Conventions, maintaining it within the ICNA Act regulations even after international listing might be appropriate. If the options identified in this Discussion Paper are preferred (i.e. enabling NICNAS to fill those ‘regulatory gaps’ in relation to industrial chemicals, which are not yet being addressed by other initiatives) there would be a stronger case for NICNAS to retain a responsibility for import and export regulations relevant to the Stockholm and Rotterdam Conventions.

Stakeholder advice is therefore sought regarding whether it is still valuable to shift responsibility for the import and export regulations, noting that a transfer of the regulations would not necessarily affect the need to continue cost recovery from industry.

Possible options for reform:

**I1.** Remove regulations relating to the import and export of Stockholm and Rotterdam Convention chemicals from the ICNA legislation, once appropriate alternative legislation has been enacted.

**I2.** Retain regulations for the import and export of Stockholm and Rotterdam Convention chemicals under the ICNA Act.

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**Input sought from stakeholders**

What are the implications of maintaining the status quo?
Governance – Committees

Currently the committee structure does not provide strategic advice for NICNAS activities as a whole, not does it include all relevant decision makers from other portfolios. There are also significant gaps in stakeholder representation. A diagram of NICNAS’ existing committee structure is included at Attachment C.

It is proposed that the roles, functions and representation of current non-statutory committees be adjusted to best support NICNAS (note the PC Report – recommendation 4.2). If NICNAS’ functions or processes change as the result of other reforms, this may influence the composition and role of the committees. It is therefore proposed that the committees be reconsidered once feedback has been obtained in relation to the other reforms. Committees will be included in the legislation where this is necessary for certainty or to best support the role of NICNAS.

Possible option for reform:

**J1.** Once the preferred reform options have been identified, consider the most appropriate role and membership of committees to best support the Director of NICNAS.

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### Input sought from stakeholders

If the options in this Discussion Paper are preferred, what does this mean for the governance committees of NICNAS?

What committees are needed? For example, would it be useful to have a strategic advisory committee advising the Director of NICNAS?

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### Relationship with the Department of Health and Ageing (DoHA)

Both the internal review and some stakeholders noted that the relationship between NICNAS and the DoHA could be improved with greater clarity around relative responsibilities (including for corporate services and policy advice).

In parallel with consideration of the possible reforms detailed in this Discussion Paper, DoHA has commenced working with NICNAS to identify ways to: clarify roles and responsibilities; improve administrative and resource efficiencies where possible; ensure that NICNAS’ staffing profile appropriately aligns with its responsibilities; and minimise any duplication of effort.

Possible option for reform:

**K1.** DoHA work with NICNAS to clarify roles and responsibilities and address any administrative and resource inefficiencies
PART 9 – NEXT STEPS

Comments sought
As noted throughout this Discussion Paper, your comments are welcome in relation to the questions raised or any other matters you consider should be taken into account in the consideration of options.

Submissions must be received by the Department of Health and Ageing by 5pm, Friday, 27 July 2012.

While submissions may be lodged electronically or by post, electronic lodgement by email is preferred. For accessibility reasons, please email responses in a Word or RTF format.

Email: NICNAS.review@health.gov.au

Mail: NICNAS Review
Department of Health and Ageing
MDP 71
GPO Box 9848
CANBERRA ACT 2601

Submissions will be made public and shared with relevant Commonwealth agencies and any consultants engaged to assist with the review.

Submissions, or parts thereof, that are intended to remain confidential should be clearly marked as such and justifications provided. Submitters should be aware that confidential submissions may still be subject to access under freedom of information law.

Next steps
During this consultation period, DoHA and DoFD will arrange workshops for face-to-face discussions with interested stakeholders. These workshops will provide stakeholders with an opportunity to share their views and ask questions about the options being suggested. Details of these workshops will be posted on the DoHA website at:

The comments received from this consultation process will be used to inform the Government of stakeholder views. These views will assist in further development of the options and will also inform the Regulation Impact Statement which will assess the costs and benefits of the options.

There will be further opportunities for stakeholder views to be taken into account, including for any proposed draft legislation.
ATTACHMENT A
SUMMARY OF OPTIONS

THE REGULATORY FRAMEWORK FOR INDUSTRIAL CHEMICALS

A1. A detailed industrial chemicals risk assessment and management manual be developed. The manual would:

– describe the roles and responsibilities of each of the agencies involved in risk assessment and management of industrial chemicals
– describe NICNAS’ processes and approach to risk assessment and management
– explain how NICNAS’ processes and approach interact with other risk assessors and managers of industrial chemicals.

A2. Following the cessation of the Standing Committee on Chemicals\textsuperscript{16}, an ongoing Australian Government cross-portfolio group be established to consider chemical policy issues for the Australian Government. The group could for example: work to minimise duplication between Australian Government agencies; identify and develop options to address ‘gaps’ in regulatory coverage; and facilitate a co-ordinated approach to risk.

A3. Memoranda of Understanding (MOU) between NICNAS and other agencies (both Commonwealth and State and Territory) be reviewed and re-negotiated (or new ones developed) to ensure clarity regarding relative roles and responsibilities.

NEW INDUSTRIAL CHEMICALS

Please note that each of the options detailed below would be likely to result in changes to the ICNA legislation (either the Act or the Regulations) as well as changes to administrative documents.

B1. In relation to all notification and assessment categories (for exemptions, permits and certificates):

• reduce the number of categories
• review current volume thresholds, data requirements and applicability criteria with a view to harmonising these with overseas

\textsuperscript{16} The Standing Committee on Chemicals (SCOC) was established by the Council of Australian Governments under a Memorandum of Understanding to achieve an effective and efficient national system of chemicals and plastics regulation. The Memorandum of Understanding establishing SCOC expires on 7 December 2014. Further information on SCOC is available at http://www.innovation.gov.au/INDUSTRY/CHEMICALSANDPLASTICS/SCOC/Pages/default.aspx
arrangements where possible\textsuperscript{17}. The objective of this would be to better clarify and harmonise data requirements and reduce complexity for industry.

**B2. In relation specifically to exemptions:**

- consider new or expanded exemptions (e.g. options described in the LRCC evaluation report on increasing the volume limits and extending the 1\% concentration exemption for non-hazardous chemicals in products)\textsuperscript{18}

**B3. In relation to permits and assessment certificates:**

- introduce a pre-assessment statutory screening process, with timeframes, to enable NICNAS to refuse an application if it does not include all the necessary information. Additional information would only be able to be provided following a request from NICNAS or under the legislative obligations to provide new relevant information (note the PC Report – recommendation 4.5).

**B4. In addition, in relation specifically to assessment certificates:**

- streamline the assessment process (note the PC Report – recommendation 4.1). For example, a model operating in the US EPA involves four distinct successive technical phases: chemistry review, hazard evaluation, exposure evaluation and the risk assessment/risk management phase. These phases are structured to ‘drop’ (from further assessment) chemicals of low risk early in the review enabling resources to focus on higher risk chemicals. As an example, polymers which meet select criteria are commonly dropped during the chemistry review. Such an approach could be considered for the assessment of new chemicals

- enable NICNAS to refuse an assessment certificate in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable level. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms

- enable NICNAS to impose conditions of use on an assessment certificate where such conditions must be removed/lifted once NICNAS receives notification from the relevant risk manager that they have implemented measures that the risk manager has determined

\textsuperscript{17} Option F1 also explores the use of foreign schemes and international assessments (Refer Part 8)

\textsuperscript{18} LRCC Reforms: An evaluation of the impact on industry Final Report, June 2009

are necessary to manage the risk\textsuperscript{19}. Any conditions of use imposed by NICNAS would only extend to the introducer (importer or manufacturer) as is the case with permits. Further, NICNAS would not impose conditions which are general obligations under, for example, work health and safety law. Conditions would only be imposed where a control is necessary beyond a generic obligation\textsuperscript{20}. For example, where a concentration limit is necessary.

**B5.** In relation to AICS:

- provide that after five years, or if the holder of an assessment certificate applies to NICNAS to have the chemical entered on AICS (to enable its introduction by anyone), require that if the chemical is subject to conditions of use (because risk management measures have not yet been imposed by the relevant risk manager) that either: the chemical not be entered on AICS until these measures are in place; or these conditions also carry over to AICS. As for assessment certificates, the conditions on AICS would be removed once other risk managers have ‘filled the gap’ (note the PC Report – recommendation 4.4)

- enable NICNAS to refuse to enter a chemical on AICS in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable limit. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms

- provide that if, during the 5 years following assessment of a new chemical, the introducer decides (for commercial reasons) to stop introducing the chemical, NICNAS may choose not to enter the chemical on AICS provided this occurs with the agreement of the company.

**B6.** Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicant’s appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

\textsuperscript{19} An alternative to this approach is to delay the issue of an assessment certificate (or delay the date of effect) until such time as the relevant risk managers have notified NICNAS that appropriate risk management strategies/conditions of use are in place. This option was not supported by the PC (refer page 70 of PC Report).

\textsuperscript{20} On the basis of a preliminary examination of past assessment certificates it is estimated that approximately 10\% of assessment certificates would include recommendations that require controls that go beyond general legal obligations.
EXISTING INDUSTRIAL CHEMICALS

Amend the ICNA Act to:

C1. Maintain the existing assessment process for PECs but remove unnecessary prescriptive detail (including, for example, the requirement for both a preliminary assessment and a full assessment).

C2. Introduce a new legislative assessment process for non-PECs. Assessment outcomes would be published to ensure transparency but the assessment process would be simplified, could be carried out in relation to more than one chemical at the same time (e.g. assessment of a group or class of similar chemicals) and assessments could be more focused. For example, assessments could focus on a particular health effect or use pattern.

C3. Broaden the mandatory information-gathering powers to enable NICNAS to better undertake risk assessment activities and to adequately manage AICS (for example, to enable NICNAS to seek information from industry in support of option C5). The circumstances under which NICNAS may request such information would need to be tightly defined and proportional to the risk. Care would also need to be taken to ensure that introducers are not required to submit the same information to multiple regulatory bodies.

C4. Remove the general power for NICNAS to impose conditions of use on chemicals after a chemical has been entered on AICS. This would be replaced with a much more limited power which would enable NICNAS to:

- impose a condition of use on a chemical listed on AICS only if an assessment of an existing chemical has been undertaken and the assessment has demonstrated that a condition of use is necessary, in order to protect public health, worker safety and the environment, and that there is no other means by which the risk can be addressed

- remove a chemical from AICS if NICNAS considers that there is unacceptable public health, worker safety or environmental risks, and risk management strategies are inadequate to manage the risk to an acceptable limit. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms21.

21 Currently NICNAS has the power to add a chemical to AICS and impose conditions if responsibility for the regulation of the chemical has been transferred from another Commonwealth regulator such as the TGA or APVMA (refer section 15AA and 15AB of the ICNA Act). If Option C4 were adopted, it is proposed that the power to ad such chemicals to AICS (and impose necessary conditions) would be retained.
C5. Establish a new Part on AICS for chemicals that are no longer being introduced into Australia. It is proposed that NICNAS would seek information from industry regarding those chemicals that have been introduced into Australia over the previous 5 years. Those chemicals that are on AICS but have not been introduced by any manufacturer or importer over the last 5 years would be placed on a separate list within AICS. If, after a further 5 years, no-one introduces the chemical the chemical would be removed from AICS following public notification and opportunity to comment.

C6. Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicants’ appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

POST MARKET MONITORING AND ENFORCEMENT

D1. Streamline the secondary notification process for existing chemicals. Consistent with the possible changes described at C2, the ICNA Act could be amended such that:

- NICNAS re-assessment following secondary notification could either occur using a streamlined approach or through the more comprehensive PEC-style approach, depending on the nature of the hazards and risks

- AICS could list the function or use of the chemical related to the original assessment. This gives clarity to the existing secondary notification obligations for significant variations to use.

D2. Supplement existing secondary notification requirements with a more comprehensive system of adverse effects reporting for new and existing industrial chemicals. Such a system would require introducers to mandatorily report adverse effects but would also enable anyone else, including users and risk managers, to report adverse effects to NICNAS. This could be similar to the APVMA system for adverse experience reporting.

D3. Introduce into the ICNA Act a comprehensive, graduated and contemporary compliance regime to enable NICNAS to better manage compliance by tailoring penalty provisions to the degree and seriousness of the non-compliance. For example, consideration could be given to the introduction of compliance tools such as assisted resolution, infringement notices and civil penalties.
OTHER REFORMS AFFECTING BOTH NEW AND EXISTING CHEMICALS

Release of information and confidential commercial information

E1. Amend the ICNA Act to enable release of information (including confidential commercial information) to other Commonwealth and state and territory agencies where it is necessary for them to fulfil their regulatory responsibilities. For example, to undertake an assessment of risk, to consider risk management strategies in relation to industrial chemicals or to monitor compliance with regulatory requirements.

E2. Amend the ICNA Act such that at the time of listing on AICS, the chemical name would be subject to contemporary confidentiality criteria to increase transparency (e.g. align with work health and safety confidentiality arrangements relating to chemical name).

Use of foreign schemes/international assessments

F1. Increase utilisation of international assessments to support and streamline the assessment for permits (noting that chemicals subject to permits are lower risk because there are ongoing post-market conditions and controls and there is a narrower set of uses)22.

F2. Better align the categories of, and data requirements for, exemptions, permits and certificates with, for example, the US, Canada and the EU23.

Chemicals in articles

G1. Clarify the role of NICNAS in relation to chemicals in articles as part of the development of the industrial chemicals risk assessment and management manual (option A1) and through the re-negotiation of MOUs where necessary (option A3).

G2. Amend the ICNA Act to clarify the role of NICNAS in the assessment of chemicals in articles, particularly imported articles.

Chemicals in cosmetics

H1. Responsibility for administration and enforcement of the Cosmetics Standard 2007 be transferred to the ACCC but the assessment of chemicals in cosmetics would remain with NICNAS

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22 This also has linkages with Option B4, streamlining the assessment process for certificates.

23 This is also discussed in relation to Option B1.
H2. New provisions could be introduced into the ICNA Act (and on AICS) to specifically deal with chemicals in cosmetics (rather than continuing to treat them like industrial chemicals). This could include a separate inventory of cosmetic ingredients, a list of ‘pre-approved’ cosmetic ingredients, a list of ingredients that are not to be utilised (based on risk), and a separate list of data requirements for the assessment of cosmetics chemicals. Better alignment with international approaches would also be explored.

Import and export of chemicals under the Stockholm and Rotterdam Conventions

I1. Remove regulations relating to the import and export of Stockholm and Rotterdam Convention chemicals from the ICNA legislation, once appropriate alternative legislation has been enacted.

I2. Retain regulations for the import and export of Stockholm and Rotterdam Convention chemicals under the ICNA Act.

Governance - Committees

J1. Once the preferred reform options have been identified, consider the most appropriate role and membership of committees to best support the Director of NICNAS.

Relationship with the Department of Health and Ageing

K1. DoHA work with NICNAS to clarify roles and responsibilities and address any administrative and resource inefficiencies
## ATTACHMENT B
### PRODUCTIVITY COMMISSION REPORT AND APPLICABLE REFORM OPTIONS

| --- | --- | --- |
| **Recommendation 4.1**
The Australian Government should impose a statutory obligation on NICNAS to ensure that:
- the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned
- its assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals. | COAG welcomes the response of the Commonwealth as set out below. Consistent with the existing legislative objective of National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Commonwealth Government agrees that assessment effort and priorities should be risk-based. New chemical assessment categories and exemptions under the NICNAS are set on a risk-based gradient. Recent new chemical reforms have introduced additional assessment options for low risk chemicals and this reform activity will continue.
The same general approach is used for existing industrial chemicals assessments, where the assessment effort can be directed to areas of potential high risk.
The NICNAS Existing Chemical Program Review recommended a systematic risk-based approach to existing chemicals assessments. Implementation is underway. To assist in directing and clearly communicating the objective that assessment effort and priorities should be risk-based, the Commonwealth will explore the potential for embedding some guiding principles in legislation and guidance.
Resource and legislative implications require further consideration in the development of an implementation plan and through the Commonwealth’s budget processes. | B1-5, C1-2, C5, D1, F1-2, and H2 |
<table>
<thead>
<tr>
<th><strong>Productivity Commission Research Report: Chemicals and Plastics Regulation, July 2008</strong></th>
<th><strong>Council of Australian Governments’ Agreed Response</strong></th>
<th><strong>Applicable Reform Option</strong></th>
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<td><strong>Recommendation 4.2</strong>  The Australian Government should establish a technical advisory committee within NICNAS, as a statutory requirement.</td>
<td>COAG welcomes the response of the Commonwealth as set out below. The Commonwealth Government supports the recommendation. The impact on governance arrangements, resources and legislative implications require analysis as part of the development of an implementation plan and the Commonwealth’s budget processes.</td>
<td>J1</td>
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<td><strong>Recommendation 4.3</strong>  The Australian Government should generally limit the role of NICNAS to the scientific assessment of the hazards and risks of industrial chemicals. The power to annotate the Australian Inventory of Chemical Substances to ban or phase out chemicals, and the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.</td>
<td>COAG welcomes the response of the Commonwealth as set out below. The Commonwealth Government agrees with the intention that the primary role of the National Industrial Chemicals Notification and Assessment Scheme’s (NICNAS) should be as a scientific risk assessment body for industrial chemicals, noting that any change to current arrangements should not introduce regulatory gaps that would weaken health and environmental protection.  In light of the Productivity Commission’s preferred governance framework, the Commonwealth Government supports further efforts to clarify the role of NICNAS and ensure that the institutional location of standard setting and risk management powers provide a cohesive and integrated industrial chemicals framework across Commonwealth and state and territory regulatory authorities.  In this regard, reducing the power of NICNAS to annotate the Australian Inventory of Chemical Substances requires further consideration to ensure that the existing levels of human health and environmental protection are maintained.</td>
<td>A1-3, B1-5, C4, D1, G1, G2, H1, I1, I2 and K1</td>
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<td>Recommendation 4.4</td>
<td>COAG welcomes the response of the Commonwealth as set out below.</td>
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<td>All relevant national standard setting bodies should be required to respond to NICNAS recommendations within defined time limits. NICNAS should maintain a public schedule of all responses.</td>
<td>The Commonwealth Government agrees with the recommendation. Requirements for national standard setting bodies to consider and respond to National Industrial Chemicals Notification and Assessment Scheme recommendations should be underpinned by formal arrangements such as Memoranda of Understanding or legislation. Resource and legislative implications require further consideration in the development of an implementation plan and through the Commonwealth's budget processes.</td>
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<td>Recommendation 4.5</td>
<td>COAG welcomes the response of the Commonwealth as set out below.</td>
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<td>The Australian Government should introduce a statutory timeframe for the technical screening of applications by NICNAS.</td>
<td>The Commonwealth Government supports the establishment of statutory timeframes for screening of applications. Resource and legislative implications require further consideration in the development of an implementation plan and through the Commonwealth's budget processes.</td>
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and that equivalent powers are established in another national body.

The Commonwealth Government supports the transfer of responsibility for implementing the Rotterdam Convention from NICNAS to the Department of the Environment, Water, Heritage and the Arts (DEWHA).

The transfer of responsibility for the Cosmetics Standard is dealt with under Recommendation 5.5.
<table>
<thead>
<tr>
<th>Recommendation 5.4</th>
<th>Council of Australian Governments’ Agreed Response</th>
<th>Applicable Reform Option</th>
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<tr>
<td>The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systematic research program to identify and deal with the risks of chemicals in consumer articles.</td>
<td>COAG welcomes the response of the Commonwealth as set out below. The Commonwealth supports the recommendation. However, the establishment of a systematic research program to identify and deal with risks of chemicals in consumer articles has resource and legislative implications for both National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Competition and Consumer Commission (ACCC) that require further consideration through the Commonwealth’s budget processes.</td>
<td>A1, A3 and G1-2</td>
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<th>Recommendation 5.5</th>
<th>Council of Australian Governments’ Agreed Response</th>
<th>Applicable Reform Option</th>
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<tr>
<td>The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.</td>
<td>COAG welcomes the response of the Commonwealth as set out below: The Commonwealth supports the intent to separate the assessment and enforcement functions associated with the Cosmetics Standard. Resource and legislative implications require consideration in the development of an implementation plan and through the Commonwealth’s budget processes. Consistent with the principles of the proposed new governance framework, the Commonwealth will explore a variation to the Productivity Commission’s recommendation that provides for separation between assessment, standard setting and enforcement.</td>
<td>H1</td>
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ATTACHMENT C
EXISTING NICNAS COMMITTEES