

**Options for reforming the National Industrial
Chemicals Notification and Assessment Scheme
Regulation Impact Statement**

**June 2013
DRAFT ONLY**

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Part A: Context

In September 2011, the Australian Government announced a review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The purpose of the review is to examine the role of NICNAS within the broader institutional and regulatory framework for chemicals regulation. The review is investigating how the regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry, and public health and environmental outcomes.

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.

In developing options for reform, the review team has taken into account:

- the review objective “to 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 principles of good regulation¹ including that any legislation:
 - be easily understood and readily accessible;
 - be risk based and proportionate;
 - avoid unnecessarily prescriptive requirements;
 - include transparent and consistent processes for making and implementing legislation;
 - not impose regulatory burdens on business that are not justified; and
- the valuable input received from stakeholders. To date, the review has included:
 - a period of public consultation between 1 November and 14 December 2011, 21 written submissions were received;
 - an internal review of NICNAS’ arrangements, functions and processes;
 - ongoing discussions with NICNAS and other Commonwealth agencies;
 - the publication of a paper titled: *Discussion Paper: Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) - June 2012*. This Discussion Paper identified a range of possible options for reforming NICNAS and sought public comment on these options, 46 submissions were received;
 - input through stakeholder engagement workshops held in Canberra, Sydney, Melbourne and Brisbane in June and July 2012. A further workshop was held on 15 October 2012 to provide key non-government stakeholders with an opportunity to comment on the regulatory impact of options for reform.
 - [Details of final consultations June/July 2013 to be added]

¹ Based on principles published by the Office of Best Practice Regulation.

Part B: Purpose of this Regulation Impact Statement

The purpose of this Regulation Impact Statement (RIS) is to assist the Australian Government to make decisions regarding any necessary reforms in relation to NICNAS.

To achieve this, the RIS assesses the impact of four options for reform and compares these options to the base case (no reform) and makes recommendations regarding a preferred option.

The RIS:

- provides background information about the chemicals industry and the role of NICNAS in chemicals regulation (Part C);
- describes the problems that give rise to the need for action (Part D);
- describes the desired objectives of any Government action (Part E);
- identifies and describes five possible options for addressing the problems and achieving Government's objectives (Part F). These options are:
 - Option 1: Base case – make no changes to the scope or activities of NICNAS
 - Option 2: Post-market emphasis on regulation
 - Option 3: Graduated, risk based approach with pre and post-market emphasis based on the risk profile of industrial chemicals
 - Option 4: As for Option 3 but with responsibility for imposition of post-market obligations resting with existing risk management agencies only
 - Option 5: Pre-market emphasis on regulation
- describes the potentially impacted parties (namely the community, industry, NICNAS and other risk management agencies) and analyses the impacts of each of the options on each of the parties (Part G);
- describes the consultation that has informed the development of the options and the RIS (Part H);
- draws a conclusion and suggests a recommended option (Part I);
- identifies a proposed approach to the implementation of the preferred option, along with opportunities for regular review (Part J).

Attachments to this RIS provide further detail about specific measures that could form part of the package of reforms.

Part C: Background – Existing regulation of industrial chemicals

The chemicals industry in Australia

Industrial chemicals have a diverse range of uses in the Australian community 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.

The chemicals and plastics manufacturing industry value added in the order of \$11.7 billion and provided about 77,079 jobs during 2010-2011².

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.

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 all government levels.

In general:

- the policy settings for government regulation of the chemicals industry are determined by ministerial councils;
- the Commonwealth undertakes most hazard and risk assessments and implements international agreements;
- 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; and
- local government involvement varies considerably, but is usually limited to planning and waste disposal issues.

² Source: Australian Bureau of Statistics, 8155.0 Australian Industry 2010-11. Based on the 2006 Australian and New Zealand Standard Industrial Classification (ANZSIC) system, Chemicals and Plastics manufacturing is here defined to include:

- Class 1709: Other Petroleum and Coal Product Manufacturing;
- Subdivision 18: Basic Chemical Manufacturing, excluding Group 184: Pharmaceutical and Medicinal Product Manufacturing; and
- Subdivision 19: Polymer Product and Rubber Product Manufacturing

Australian Government chemicals assessment and registration schemes

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

- industrial chemicals are notified to, and assessed by, 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); and
- 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.

Role of NICNAS

Overview

NICNAS administers the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act).

The primary role of NICNAS in the chemical regulatory framework relates to risk assessments of industrial chemicals. The information generated from an assessment aids in the protection of the Australian people, and the environment, by identifying risks to worker health and safety, public health and the environment and making recommendations for their safe use.

Under the ICNA Act, new industrial chemicals cannot be introduced into Australia unless they have been notified to, or assessed by, NICNAS and either a permit or certificate has been issued, or meets the requirements for introduction without notification (an 'exemption').

In relation to some industrial chemicals, NICNAS plays a risk management role by issuing permits and certificates to enable the introduction of certain industrial chemicals that may be subject to risk management conditions.

In other cases NICNAS provides its risk assessments, and any resulting recommendations for risk management controls, to the government risk management agencies which then determine the controls to enact and enforce.

Recommendations are also provided to the notifier or applicant and they are expected to voluntarily comply with the recommendations.

NICNAS maintains a list of 'existing chemicals' called the Australian Inventory of Chemical Substances (AICS). NICNAS can undertake a risk assessment of existing chemicals in specific circumstances.

Details of each of these components of NICNAS' role are described below.

Industrial chemicals

The chemicals that fall within the jurisdiction of NICNAS are determined on an exclusions basis. Industrial chemicals are chemicals that are not:

- a pesticide or veterinary medicine;
- a therapeutic good; or
- a chemical in foods or a food additive.

NICNAS is a chemical substance regulator, which means that it assesses the individual ingredients found within products, rather than the end use product.

New chemicals - Notification and assessment activities

Currently, under 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); or
- 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:

- ***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 2011-12, 5,882 chemicals were reported to be introduced through exemptions³.

- **permits** are available for chemicals that meet other legislated 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 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 2011-12, 150 permit applications were received by NICNAS and 114 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. 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. The NICNAS assessment report includes hazard identification, risk assessment and recommendations for regulatory controls and conditions of use.

Once NICNAS issues an assessment certificate, the introducer is able to introduce the chemical into Australia. Unlike for permits, NICNAS does not have the power to refuse an assessment certificate, nor does it have the power to impose enforceable 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 management agencies.

In a period of analysis from September 2010 to September 2012, NICNAS issued 264 certificates for new chemicals. Of these, NICNAS recommended that risk management measures be implemented by risk management agencies for 60 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.

A chemical on AICS (an existing chemical)⁴ can be declared a Priority Existing Chemical (PEC) which provides for a closer examination and a detailed risk

³ 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.

⁴ A naturally occurring chemical is deemed to be on AICS.

assessment to determine if there are potential risks and if these risks are adequately managed. A PEC assessment results in a report and recommendations for risk management.

There are approximately 39,000 chemicals on AICS, most of which were included on AICS based on their use prior to the commencement of the scheme, and have not been assessed by NICNAS for their health and environmental impacts.

- **secondary notification** - During the validity of a certificate (usually 5 years), the introducer is obliged to report to NICNAS changed circumstances (to those considered in the assessment) which may necessitate a reassessment of the chemical. These obligations also apply for assessed chemicals on AICS. The onus is on the importer or manufacturer to inform the Director when a change in circumstance occurs. Following receipt of this information, the Director may require reassessment (Secondary Notification) of the chemical. 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). In 2011-12 NICNAS received 4 secondary notifications.
- **registration** - All introducers of industrial chemicals for commercial purposes must register with NICNAS, regardless of the amount of imported or manufactured industrial chemical, although the registration charge payable depends on the value of the industrial chemicals being introduced in a year. The register of introducers allows NICNAS to keep industry informed of obligations and any changes that may take place. In 2011-12 there were 5002 registered introducers of relevant industrial chemicals.

Compliance and enforcement

NICNAS monitors compliance with the ICNA Act including compliance, by introducers, with requirements relating to the introduction of new industrial chemicals, chemicals under permit and company registration.

The ICNA Act provides the Director of NICNAS with certain powers to support its compliance and enforcement role, including:

- powers to mandatorily call for information relating to the introduction of a new industrial chemical by registered or unregistered persons;
- powers to request information in relation to a new chemicals assessment process, a priority existing chemicals process and administration of the Rotterdam Convention;
- powers to request any information relating to registration; and
- powers for inspection, search and seizure with either consent of the occupier of the premises, or a warrant.

The ICNA Act also provides for penalties for non-compliance with specific sections (that may be applied by a court of law following a successful prosecution).

In 2010-11 NICNAS, as part of its compliance program, 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.

Interaction with Commonwealth and State/Territory risk management agencies

The ICNA Act assumes, for industrial chemicals not covered by an exemption or permit, that the Commonwealth, state and territory risk management agencies will use the information arising from the risk assessment of new and existing chemicals to determine and implement practical controls on the use, release and disposal of industrial chemicals under their regulatory frameworks. These areas of regulation include:

- public health through the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard);
- work health and safety: Safe Work Australia is a national policy setting body whose key role is to improve work health and safety and workers' compensation arrangements across Australia. Commonwealth, states and territories agencies regulate and enforce work health and safety laws in their jurisdiction;
- environmental management: Commonwealth, state and territory agencies monitor and manage industrial chemicals in the environment⁵;
- the land transport of dangerous goods, which is regulated under state and territory legislation that reflects the Australian Code for the Transport of Dangerous Goods by Road and Rail (the Code); and
- consumer product safety: the Australian Competition and Consumer Commission (ACCC) has responsibility for the regulation of consumer goods, which are products for personal, domestic or household use⁶.

⁵ 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.

⁶ Cosmetic products imported into, or manufactured in, Australia are also regulated under the ICNA Act (Part 3B)

In the course of settling its recommendations, NICNAS may interact directly with over 36 government departments, agencies and intergovernmental coordinating schemes and must have regard to the different priorities that exist within each jurisdiction as well as differences in legislation and intra-agency responsibilities. Consistent with the recommendations of the Existing Chemicals Program Review, NICNAS allocates resources and effort towards consultations with risk management agencies, including facilitating the take up of recommendations⁷.

⁷ [Reforming NICNAS's Existing Chemicals Program Review](http://www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program.asp)
(www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program.asp)

Part D: The problem or issue that gives rise to the need for action

The purpose of this RIS is to assist the Australian Government to make decisions regarding issues relating to the notification and assessment of industrial chemicals.

The Productivity Commission in *its 2008 Chemicals and Plastics regulation Research Report* also identified concerns regarding the broader regulatory environment for chemicals which involves over 140 pieces of legislation and a complex, fragmented system with no common risk framework.

As the Better Regulation Ministerial Partnership, which was informed by this RIS, focuses specifically on NICNAS and the assessment and regulation of industrial chemicals, this RIS does not address the institutional and regulatory arrangements for chemicals more broadly.

Three main problems are identified with the existing regulatory framework for the notification and assessment of industrial chemicals:

- the assessment framework is not sufficiently risk based;
- the legislative requirements create inefficient regulatory processes which cause unnecessary regulatory burdens on industry for no improvement in regulatory outcome; and
- there are inconsistencies and uncertainties in regulatory coverage.

Further detail on each of the problems is described below.

Assessment framework is not sufficiently risk based

The assessment framework does not adequately take into consideration the potential risk of a new chemical in the level of assessment required for introduction.

Stakeholders suggest that the ICNA Act unnecessarily focuses on low risk chemicals. This has a range of consequences and presents problems in relation to both pre and post-market regulatory activity. For example, this means that:

- the pre-market regulatory effort does not substantially differ between high and low risk chemicals and the scope of the assessment is not proportionate to the level of risk posed by a chemical in pre-market assessments;

For example, during consultations an industry representative provided the example of two chemicals assessed by NICNAS. The first chemical was not hazardous to human health or the environment and was intended to be used in industrial applications (mining, steel milling, printing). The second chemical was considered hazardous (classified as a skin sensitiser) and was to be used in a fragrance ingredient. Under the current ICNA Act, the assessment process was the same for both chemicals. This meant that the introducers of

both chemicals have the same regulatory treatment despite the difference in the risk posed by each chemical.

- low risk chemicals are subjected to an intensive pre-market risk assessment process that is unnecessary and creates heightened compliance cost to industry that is not proportionate to the potential risk posed by the chemicals;

For example, industry has noted that there are high pre-market regulatory requirements for low risk chemicals (e.g. chemicals introduced in amounts of less than 1000kg), particularly when compared with comparable overseas regulators. To meet the pre-market requirements, introducers of low risk chemicals (that are already available overseas) are required to undertake additional testing which is expensive and therefore impacts on the financial viability of introduction.

- many chemicals that are widely used in manufacturing or in products in international jurisdictions, are still subject to full assessment by NICNAS. This issue is particularly relevant, when a chemical has been subject to assessment or evaluation in jurisdictions such as Europe and or North America or where it is allowed to be used in New Zealand;
- post-market obligations, on introducers, are not aligned to risk; and

For example, for chemicals that have been assessed and are subject to secondary notification, the circumstances in which secondary notification is required are not clear because AICS does not list the function or use of the chemical that was subject to assessment.

For those chemicals that are on AICS and have not been assessed by NICNAS there are no secondary notification requirements. The result of this is that there are different post-market obligations based on when the chemicals was first introduced rather than on the risks posed by the chemical.

- the legislative assessment process for existing chemicals (including assessment following secondary notification) is the same regardless of the issue identified through secondary notification and the risk posed by the chemical.

The legislation describes a mandatory process for the post-market assessment of existing chemicals – known as the Priority Existing Chemical (PEC) process.

While the PEC process may be appropriate for chemicals of national significance, it is not appropriate for all assessments of existing chemicals because the process is detailed, resource intensive and lengthy. The process does not enable an efficient assessment of a chemical.

Although NICNAS can adopt non-legislative assessment processes to increase flexibility, the mechanics and outcomes of this approach lack regulatory certainty for NICNAS and stakeholders.

Since AICS was established in 1990, NICNAS has completed 34 assessments of PECs covering around 200 chemicals⁸.

Legislative requirements create inefficient regulatory processes

The ICNA Act is very prescriptive in the requirements for notification and assessment of new and existing industrial chemicals. This creates inefficiencies in the regulatory process, specifically:

- the new chemicals notification framework is overly complex and restrictive;

For example, the new chemicals notification framework has more than 30 different categories for exemptions, permits and certificates. This has the potential to be confusing and leads to inefficiencies for both industry and NICNAS.

- the legislation does not enable NICNAS to reject an application that does not include the necessary information. Additional information can also be submitted to NICNAS at any time, which is inefficient, delays the assessment process and adds to costs, including costs to industry;

For example, the Australian Paint Manufacturers' Federation notes that the requirement for all applications to be assessed, including those that do not contain the necessary information, applies unnecessary pressure on the statutory assessment timeframes. The completion of these information deficient applications negatively affects NICNAS' new chemical assessment timeframes.

- the legislation places detailed and unnecessarily costly requirements on the assessment of chemicals already on the market. As noted above, the legislated PEC process is not efficient, is time consuming and the assessment effort is not aligned with the potential risk; and
- NICNAS' ability to identify non-compliance and respond in an appropriate manner is limited under the Act. Specifically, the information-gathering powers in the ICNA Act are limited and do not adequately enable NICNAS to request and obtain information necessary to inform its assessment of either compliance or risk.

For example, the circumstances under which NICNAS can mandatorily call for information on uses, volumes and effects of existing chemicals are limited. The nature of this information means that it is not information that can be determined by observation or is publicly available and reliance on voluntary provision of such information creates uncertainty in assessment outcomes.

Stakeholders expressed the view that NICNAS' enforcement and compliance tools are currently not proportional to the risks posed through non-

⁸ [Priority Existing Chemical assessment reports](http://www.nicnas.gov.au/Publications/CAR/PEC.asp) – (www.nicnas.gov.au/Publications/CAR/PEC.asp)

compliance or the seriousness of the offence. Further, the tools available are currently limited compared to those available to other regulators. There is no intermediate regulatory tool available to NICNAS between administrative notices (informal) and pursuing a prosecution to impose a criminal penalty.

Inconsistencies and uncertainties in regulatory coverage

The structure of the ICNA Act and its interaction with the broader chemical regulatory framework creates inconsistencies and uncertainties as they relate to industrial chemicals.

NICNAS makes recommendations to risk management agencies about risks posed by industrial chemicals, both new and those already on the market, to inform the development of necessary risk mitigation actions to protect human health and the environment.

During consultations, environmental, public health, workplace health and safety and government stakeholders highlighted situations where there is:

- a time lag between NICNAS' assessment of a chemical and a regulatory risk manager's implementation of a NICNAS recommendation. Risk management agencies may take time to impose conditions of use, resulting in a period of regulatory uncertainty (i.e. a gap in regulatory coverage). In a previous review of the uptake of NICNAS existing chemical recommendations, jurisdictions indicated that resources for chemical management are limited. While some recommended changes can be implemented quite quickly (for example, taking eight weeks), recommendations that require legislative or regulatory change, or where a Regulation Impact Statement needs to be prepared, can take much longer (up to two years or more). Throughout this period, the chemical can be introduced into Australia without regulatory controls in place and instead relying on industry to voluntarily comply with any NICNAS recommendations (discussed below).

For example, the NICNAS Community Engagement Forum noted that following a PEC assessment by NICNAS of formaldehyde in November 2006, over the last 6 years there has been incomplete uptake of NICNAS' recommendations by risk management agencies which the forum considers has meant that the environment, workers and the public have most likely been (and are continuing to be) exposed to unsafe levels of formaldehyde through inadequate workplace health and safety advice, incorrect classifications and labelling and a failure to set appropriate environmental and health standards.

In 2011-12 NICNAS issued 174 certificates for new chemicals. Of these, NICNAS recommended that risk management measures be implemented by risk management agencies for 56 chemicals. These agencies do not report to NICNAS when they have implemented recommendations so it is not possible to systematically identify, for each case, what the time lag was between introduction of the chemical and application of regulatory conditions by the relevant risk management agencies.

Industry stakeholders reported that where NICNAS makes recommendations industry voluntarily follow them, particularly given the general regulatory obligations relating to worker safety, product safety and avoiding environmental damage. However, in the absence of enforceable conditions imposed by risk management agencies, evidence of actual harm would be required before action could be taken which is contrary to the preventive purpose of the regulation of industrial chemicals. There is also a risk that if misuse were to occur it would be challenging for regulators to prosecute where warranted;

- no agency able to be identified as the appropriate risk management agency;

For example, NICNAS recently undertook a new chemical assessment involving a water purification chemical for home water filters. NICNAS made recommendations (for conditions to be applied) but there was no relevant risk management agency. In the absence of a risk management agency, NICNAS recommendations were directed more generally towards industry and management of the risk was reliant on voluntary adoption.

- no capacity for NICNAS to refuse to issue an assessment certificate or to refuse to enter a chemical on AICS, based on risk. This means that a chemical can be introduced, and in cases of a chemical on AICS, continue to be introduced and widely used, regardless of whether the chemical poses an unacceptable public health, worker safety and/or environmental risks and despite any possible risk mitigation by risk management agencies;
- a lack of communication and information sharing between NICNAS and related risk management agencies; and

For example, anecdotal evidence from risk management agencies involved in managing the impact of chemicals suggests that there is sometimes limited information available to them on chemicals and that this makes setting risk management decisions challenging. This is because, due to confidentiality provisions in the ICNA Act, NICNAS is unable to share certain information about chemicals (including in some cases their uses, composition or chemical name).

Stakeholders also highlighted the difficulties inherent in secondary notifications if there is no information on AICS about the use assessed for a chemical.

- there is a lack of clarity about the original assessment meaning that introducers using chemicals previously assessed are not always aware of the scope of the original assessment and therefore whether they are operating outside that scope, and needing to notify NICNAS

For example - one stakeholder noted that due to confidentiality issues, it is currently difficult to find out whether secondary notification of a chemical is needed, as the second manufacturer or importer has no access to information about the scope of the original assessment.

In essence, the key problem with the existing regulatory scheme is that it is not well aligned to risk and it is inefficient. This leads to problems in terms of pre-market assessment, post-market activity and in NICNAS' relationships with other regulators.

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Part E: The desired objectives

Consistent with the problems identified in the previous Part, the core objectives of any reform are to:

- better align NICNAS regulatory effort with the risk of the industrial chemical. That is, ensure an appropriate risk continuum, with regulatory effort (both pre- and post-market) matched to risk;
- address ‘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; and
- improve the overall efficiency of NICNAS’ processes and remove unnecessary regulatory imposts.

In achieving these objectives, any government action must also:

- ensure appropriate levels of protection for public health, worker safety and the environment;
- encourage competition and innovation in the industrial chemicals industry by removing unnecessary regulation and minimising the cost of regulation to industry;
- provide greater clarity, certainty and transparency for industry, consumers, governments and NICNAS; and
- preserve and not disrupt the important role of risk management agencies, noting the complexity of the regulatory system for chemicals, while minimising unnecessary duplication of regulatory effort.

Part F: The options

The options

Five possible options have been identified. Aside from Option 1 (base case), each of the options involves re-aligning the risk-based regulation and creating efficiencies in the risk assessment and management process.

- Option 1: Base case – make no changes to the scope or activities of NICNAS.
- Option 2: Focus regulation on post-market controls.
- Option 3: Graduated, risk based approach with pre and post-market emphasis based on risk profile of chemicals.
- Option 4: As for Option 3 but with responsibility for imposition of post-market obligations resting with existing risk management agencies.
- Option 5: Pre-market emphasis on regulation.

Each of these options is described in more detail below.

Description of the options

Option 1: Base Case

This option would see no changes made to the current focus of regulatory effort for NICNAS. The scope of activities and responsibilities of NICNAS would remain as they are described in Part C. This is considered to be a base case.

Option 2: Focus regulation on post-market controls

This option involves the following.

- Reducing pre-market barriers to the introduction of new chemicals by focusing regulatory action on post-market monitoring rather than pre-market assessment by NICNAS.
- Significantly expanding the chemicals exempt from regulation or subject only to notification to NICNAS (following self-assessment against risk-based criteria). This would include certain chemicals approved by other recognised regulatory authorities and would allow a wider range of new chemicals to be introduced

immediately following notification to NICNAS without the delays associated with assessment. It would also remove the need for permits.

- Requiring introducers to provide an annual declaration of compliance, confirming continuity of the original notification's attributes and empowering NICNAS to audit the declarations associated with notifications. The results of the auditing could be used to inform the development of criteria for the introduction of chemicals.
- Retaining the capacity for NICNAS to undertake a detailed assessment of a limited range of high risk chemicals, but limiting NICNAS' role to one of risk assessment only. The capacity for NICNAS to impose any controls (e.g. volume or use) would be removed but NICNAS would retain the capacity to make recommendations to risk management agencies. Similarly, NICNAS could undertake an assessment of an existing chemical on AICS, or reassessment of a previously assessed chemical, but its role would be as a risk assessor only. NICNAS would, however, be able to make recommendations to other risk management agencies.
- Consistent with removing NICNAS' power to impose limitations on use for new chemicals (i.e. removal of permits), any limitations on the use of existing chemicals (other than particulars of use) would be removed.
- Strengthening NICNAS' post-market powers to take action in the event of non-compliance. This would include:
 - aligning any offence provisions with similar Australian Government regulatory frameworks; and
 - enabling NICNAS to require introducers (i.e. regulated entities) to produce information.

Option 3: Graduated, risk based approach with pre and post-market emphasis based on risk profile of chemicals

This option involves the following:

- NICNAS adopting a graduated, risk-based approach to the regulation of industrial chemicals such that the level of regulatory intervention (either pre-market or post-market) matches the anticipated level of risk posed by the industrial chemical and its use.
- There being four classes of industrial chemicals each with different pre and post-market requirements:
 - Class 1: Chemicals that are excluded from the NICNAS regime entirely.
 - Class 2: Chemicals that are considered to be very low risk (or proposed to be used for low risk uses) and so are eligible for automatic market entry

(no pre or post-market NICNAS requirements, provided that the chemical meets prescribed, risk-based criteria).

Class 3: Chemicals that are considered to be relatively low risk and so are eligible for self-assessment and notification to NICNAS (pre-entry notification based on self-assessment against simple, objective criteria, post-entry annual declaration of compliance by introducer and post-entry auditing by NICNAS).

Class 4: Chemicals that are potentially medium or high risk or present significant uncertainty (for example, because of gaps in data) and are therefore subject to notification and NICNAS assessment (pre-market entry approval by NICNAS and post-market auditing by NICNAS).

- NICNAS undertaking pre-market assessment of Class 4 new industrial chemicals only. For these chemicals:
 - the assessment process would be streamlined;
 - NICNAS would consider international use and exposure data to determine whether it is appropriate and reliable in the Australian context, but NICNAS would not automatically issue a certificate for a new industrial chemical on the basis that it has been approved by another regulatory authority. Similarly NICNAS would not automatically ban or restrict a chemical that has been banned or restricted in another country;
 - the Director of NICNAS would consult with a proposed risk management advisory committee (see ‘*Other matters*’ below) in relation to the adequacy of risk mitigation measures;
 - the regulatory outcome would be either:
 - issue of a certificate with or without particulars of use and limitations on introduction (such as volume and concentration); or
 - refusal to issue a certificate if the risks cannot be managed, either by limitations on introduction, or by the imposition of risk management conditions by risk management agencies
 - NICNAS would be able to make recommendations to risk management agencies in connection with the issue of any certificate.
- NICNAS undertaking an assessment of an existing chemical on AICS, or reassessment of a previously assessed chemical in three circumstances:
 - in response to a request from a certificate holder to vary a certificate. For example, to expand the particulars of use or remove or change a limitation relating to, for example, volume or concentration;
 - in response to a request from an introducer to vary the particulars of use of a chemical on AICS; and
 - at NICNAS’ own initiative.

- Providing NICNAS with more appropriate post-market tools – Specifically expanding NICNAS current post-market auditing activities by:
 - aligning any offence provisions with similar Australian Government regulatory frameworks;
 - enabling improvement notices and prohibition notices to be issued in response to non-compliance; and
 - enabling NICNAS to require introducers (i.e. regulated entities) to produce documents.

Option 4: As for Option 3 but with responsibility for imposition of post-market obligations resting with existing risk management agencies

This option is the same as Option 3, except that NICNAS would not have the power to refuse introduction or impose any limitations on use following an assessment of either a new chemical, or an existing chemical.

Recommendations would be made to relevant risk management agencies (if any) and where there are no relevant risk management agencies, the matter would be referred to a risk management agency agreed by all States and Territories following a period of negotiation. During any time-lag the chemical could be introduced, and the introducer would be expected to voluntarily comply with any recommendations of NICNAS.

Option 5: Pre-market emphasis on regulation

This option would rebalance the regulatory effort towards pre-market assessment of new chemicals. This option involves the following:

- Continuing to allow very low risk chemicals to be subject to exemptions and notifications, but with the default position being assessment by NICNAS (rather than the default position being notification and introduction as per Option 2).
- Strengthening the role of NICNAS as a risk management agency by enabling NICNAS to impose any conditions on the introduction of any chemical assessed by NICNAS where this is warranted based on worker safety, public health or environmental grounds.
- Providing the Director of NICNAS with the power to refuse or revoke a permit or certificate to introduce a chemical (even after the chemical had been introduced) if it was deemed to present an unreasonable risk to humans and/or the environment.
- Providing NICNAS with more appropriate post-market tools – Specifically:
 - aligning any offence provisions with similar Australian Government regulatory frameworks;

- enabling improvement notices and prohibition notices to be issued in response to non-compliance; and
- enabling NICNAS to require introducers (i.e. regulated entities) to produce documents and appear before the Director of NICNAS to answer questions.

Key differences between the options

The key differences between the options relate to the focus of regulatory control (both ‘when’ the regulatory control is imposed, and ‘who’ imposes the regulatory control):

- Option 2 focuses on post-market controls, with most chemicals subject to automatic entry following notification, and a very limited class of chemicals subject to pre-market assessment. Those few chemicals subject to pre-market assessment would not be subject to any risk management conditions imposed by NICNAS, but NICNAS would retain the ability to make recommendations to risk management agencies. Under this option NICNAS’ focus would be on risk assessment (as it would have no risk management functions), and on monitoring industry compliance with pre-market self-assessment and notification requirements;
- Option 5 focuses regulation on pre-market controls with only limited chemicals eligible for entry based on notification only, and the default position being assessment by NICNAS. Under this option NICNAS is also able to impose risk management conditions. Essentially this option increases the role of NICNAS in both pre-market risk assessment and risk management;
- Option 3 is a combination of Options 2 and 5 whereby NICNAS: reduces the level of pre-market assessment (based on risk); retains the capacity to undertake risk assessment for potentially high risk chemicals; and has the capacity to impose limitations on use where this is necessary to fill a regulatory gap, without usurping the role of existing risk management agencies; and
- Option 4 is a variation on Option 3 whereby NICNAS reduces the level of pre-market assessment (based on risk); retains the capacity to undertake risk assessment for higher risk chemicals; but does not have the capacity to refuse to allow the introduction of a chemical into Australia or to impose limitations on use in order to manage risk. This would be the role of other risk management agencies only. Where there is no other agency, States and Territories would negotiate to identify an agency.

Options 2 to 5 would all involve improvements to streamline NICNAS’ risk assessment processes.

Other matters

During consultations undertaken as part of the review of NICNAS, options were also discussed regarding governance arrangements, including certain changes to regulatory responsibility for cosmetics, and the import and export of chemicals, and in relation to internal NICNAS governance.

These changes were not controversial and do not fundamentally affect the nature and type of regulation employed by NICNAS.

It is therefore proposed that these changes proceed regardless of which reform option is preferred.

These changes include:

- *Chemicals in articles and mixtures* – It is proposed that the Act be amended to further clarify that an article or a mixture of chemicals is not subject to NICNAS regulation per se. However, individual new and existing chemicals in mixtures are subject to the proposed framework, as are chemicals that are released or leach from articles.
- *Chemicals in cosmetics* - It is proposed that the ACCC take on responsibility for administration of the Cosmetic Standard 2007. NICNAS would continue to regulate the introduction of industrial chemicals for use in cosmetics but would not regulate the end use cosmetic product. Further consultation would be undertaken by ACCC in relation to the nature of the regulation proposed in relation to cosmetic products.
- *Responsibilities under the Stockholm and Rotterdam Conventions*
 - It is proposed that regulation of the import and export of chemicals in accordance with the Rotterdam Convention be removed from the ICNA framework. This would become the responsibility of the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC).
 - Under the Stockholm Convention NICNAS, currently, has no import or export related responsibilities. Rather, NICNAS takes into account Persistent Organic Pollutant (POPs) criteria specified in the Convention, when undertaking assessments of new and existing chemicals. It is proposed that NICNAS would continue to do this under any of the proposed options.
- *Interactions with risk management agencies*
 - It is proposed that greater opportunity for NICNAS to interact with risk management agencies will be incorporated in revised processes. This will include ensuring the appropriate sharing of information between NICNAS and risk management agencies where it is necessary to fulfill regulatory functions.
 - It is proposed that NICNAS will maintain a register of the responses of risk management agencies to NICNAS recommendations. Risk management

agencies' responses will be reported at a defined time following the issuing of an assessment certificate.

- *Establishment of a risk management advisory committee* - It is proposed that a non-legislative committee be established consisting of NICNAS and the national risk management bodies dealing with work health and safety, public health, environment, transport and consumer safety. The committee would consider issues relating to risk management recommendations and NICNAS' relationship with risk management agencies. Issues and view from relevant state and territory risk management agencies will be collated through the national risk management bodies.

The Director of NICNAS would remain able to convene advisory committees, and participate in cross-jurisdictional committees established by other agencies, on issues related to the notification and assessment of industrial chemicals, and interactions between risk assessment and risk management activities.

Part G: Analysis of impacts

Potentially impacted parties

The potentially impacted parties include:

- the community;
- industry;
- NICNAS; and
- other risk management agencies.

Each of these parties is described briefly below.

Community:

Given the diversity and reach of industrial chemicals in our society, and the associated risks to human health and the environment, the entire Australian community is potentially affected by industrial chemicals and is therefore impacted by any changes in regulation.

Industry:

The chemicals industry directly employs over 53,000 people and represents between nine and ten percent of total Australian manufacturing activity⁹. 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. As at 30 June 2012, there were 5,002 businesses registered with NICNAS as manufacturers or importers of industrial chemicals in Australia.

NICNAS:

The Director of NICNAS is supported by departmental staff with costs fully recovered through industry fees and charges for assessments and registrations. The annual operating budget is approximately \$10 million.

Other risk management agencies:

Recommendations for risk management of industrial chemicals are currently referred to an appropriate government risk management agency (Commonwealth, State, Territory agencies). These agencies then develop the recommendations into practical requirements to control the use, release and

⁹ [Department of Innovation, Industry, Climate Change, Science, Research and Tertiary Education](http://www.innovation.gov.au/Industry/ChemicalsandPlastics/Pages/default.aspx).
(www.innovation.gov.au/Industry/ChemicalsandPlastics/Pages/default.aspx)

disposal of industrial chemicals. 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);
- work health and safety: Safe Work Australia is a national policy setting body whose key role is to improve work health and safety and workers' compensation arrangements across Australia;
- environmental management: Commonwealth, state and territory agencies monitor and manage industrial chemicals in the environment¹⁰;
- the land transport of dangerous goods, which is regulated under state and territory legislation that reflects the Australian Code for the Transport of Dangerous Goods by Road and Rail (the Code); and
- 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.

Option 1: Base case

In summary, this option retains the status quo as described in Part B.

Community

As the option maintains the status quo, it is not expected that there would be any change (increase or decrease) in the risk to workers, public health or the environment.

In terms of the three main problems identified in Part C (regulatory effort not being matched to risk, the existence of regulatory 'gaps' and inefficient regulatory processes), these problems would continue to exist.

The potential impacts of this, from a community or environmental perspective, include the following:

- continued gaps in regulatory coverage. During consultations consumer and environmental stakeholders expressed concerns that while NICNAS can make recommendations to risk management agencies about risks posed by industrial chemicals, the risk management agencies may take time to impose conditions of use, resulting in a 'gap' in regulatory coverage during that period. Stakeholders also expressed concern about the circumstances in which there is no appropriate risk management agency, and therefore no way to enforce the necessary condition

¹⁰ The Council of Australian Governments agreed to develop 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.

of use, in order to minimise risk to public health, worker safety and the environment. These concerns would continue if the status quo were maintained;

- flow on effects as the result of impacts on business. For example, businesses have reported that:
 - there are higher product costs, resulting from the reported high compliance costs that businesses face and that this has the potential to impact costs of chemicals to businesses and ultimately consumers;
 - the current scheme inhibits the introduction of new, safer chemicals and there may be an impact on the public, workers and the environment if the potential benefits of new chemicals are not realised;
- potential indirect impacts on the public from not amending NICNAS' regulatory tools. The concern that NICNAS is unable to adequately collect information to inform existing chemical reviews and address non-compliance would continue; and
- as existing chemical reviews would be expected to continue to be time-consuming (several years per chemical), uncertainty would still remain about the impact of continuing to use existing, unassessed chemicals that were grandfathered onto AICS at the commencement of NICNAS or used in new ways or new environments without being reassessed for risk by NICNAS.

Industry

Industry has reported that existing pre-market regulatory requirements are unnecessarily costly and slow. The limitations on NICNAS, which lead to significant delay in addressing the risk posed by existing chemicals, further encourage the continued use of chemicals already on the market.

If no changes are made to regulatory requirements for business, industry will be required to continue to fulfil current regulatory requirements. Industry representatives noted that the consequence of the failure to adequately align the processes with risk (and the cumbersome regulatory process) is unnecessary costs to business including:

- elapsed time costs;

Affected businesses have reported that the elapsed time prior to receiving NICNAS approval can present a significant barrier to introduction of chemicals to the market. This is because there is often only a short time-window in which a business can take advantage of an innovation, and elapsed timeframes associated with NICNAS assessments can be over six months.

The industry reported that elapsed time includes preparation of information prior to submitting the notification to NICNAS and responding to follow up issues that may arise during the assessment process. Although some of these issues are

outside of the scope of NICNAS' statutory timeframes, from an industry perspective, the total elapsed time represents the time cost of the current regulatory requirements. This is illustrated in the table below.

Table 1-1 - Elapsed time to prepare for, notify and then receive assessment of notifications and permits compared with statutory timeframes¹¹

Regulatory cost	Standard/limited notification	Polymer of low concern	Permit
Estimated elapsed days	Min: 187 Max: 200	Min: 73 Max: 80	Min: 73 Max: 80
NICNAS' statutory assessment timeframes	Min: - Max: 90	Min: - Max: 90	Min: 14 Max: 28

Taking into consideration both the assessment fees and regulatory effort, as reported by industry during consultation, the regulatory costs associated with the introduction of a new industrial chemical under a standard or limited certificate is in the range of \$39,000 - \$67,000.

- reformulation costs; and

Industry has reported that reformulation costs are associated with changing a chemical product's ingredients in response to (or in anticipation of) NICNAS' regulatory approvals processes. Although it was considered possible that products were reformulated to avoid NICNAS assessment of new chemicals, businesses interviewed were not able to quantify the extent or frequency with which this occurs.

- opportunity costs.

Industry has reported opportunity costs associated with lost sales and also consumer access to potentially safer chemistry. Industry stakeholders have suggested that, due to the complex and costly nature of the regulatory approvals, they may avoid dealing with NICNAS and decide not to bring a chemical into Australia. This affects both businesses that will be unable to sell a particular new chemical, as well as end-users of the chemical in Australia, who have reduced access to new, and potentially less hazardous, chemicals that are developed internationally.

Finally, industry highlights the cost of existing post-market annual reporting requirements which industry perceive to be overly onerous, but which public and environmental health professionals argue is insufficient.

¹¹ Source: Identified by industry stakeholders interviews, undertaken by KPMG in 2012.

The extent of these impacts depends on the level of contact business has with NICNAS. Smaller businesses may also be impacted to a greater extent than larger businesses, as larger businesses typically have more resources to deal with regulatory requirements.

In terms of post-market impacts, if there were no changes to NICNAS' current post-market regulatory tools:

- the absence of accurate use data will result in the potential that existing chemical reviews will be informed by conservative estimates, resulting in more risk averse recommendations to risk management agencies. These recommendations may increase the regulatory costs for industry; and
- retention of the existing compliance tools will continue the likelihood that the level of an offence is not matched to an appropriately severe penalty. Industry may, therefore, not have sufficient incentive to comply with requirements.

NICNAS

Maintaining current regulatory processes will mean that inefficiencies in government processes will continue. Regulatory effort spent on assessing chemicals is not currently proportionate to the risk of the chemicals. Current arrangements mean that processes are lengthy and inefficient increasing costs and delays for industry and limiting NICNAS' ability to protect public health and the environment (through timely assessment of higher risk chemicals).

NICNAS' current regulatory tools are inadequate to effectively undertake its expected role. Specifically, NICNAS' limited powers to gather and request information together with restricted compliance and enforcement tools result in inefficiencies that hinder NICNAS' ability to adequately fulfill its function.

Other risk management agencies

The status quo would mean no change to existing risk management agencies. Existing risk management agencies would continue to receive recommendations from NICNAS regarding industrial chemicals. It would continue to be up to those risk management agencies to decide whether they act on any recommendations of NICNAS and if so, when they act.

It is expected that there would continue to be a level of confusion about the limitations on the role of NICNAS compared to the role of risk management agencies. For example, some stakeholders do not perceive NICNAS as currently having any risk management role, despite the fact that:

- in 2011-12, NICNAS issued 114 permits, all containing limitations on use;

- in 2011-12 NICNAS issued 174 certificates for new chemicals. Of these, NICNAS recommended risk management measures be implemented by risk management agencies for 46 chemicals.

AICS also contains 64 existing chemicals with limitations on use. For example, chemicals that have been transferred from TGA.

Risk management agencies would continue to experience difficulties in fulfilling their regulatory responsibilities due to limited information on the risks posed by industrial chemicals being introduced, e.g. difficulties linking AICS entries with risk assessment reports.

Option 2: Post-market emphasis

In summary, this option significantly expands the number of chemicals exempt from regulation or subject only to notification to NICNAS (following self-assessment against risk-based criteria). This would include chemicals approved by other recognised regulatory authorities. This would allow a wider range of new chemicals to be introduced immediately following notification to NICNAS and would also remove the need for permits. Post-market monitoring and enforcement activity would be increased.

Community

As the focus of this option is on post-market monitoring rather than pre-market risk assessment, the general public, workers and the environment will bear the burden should there be any incorrectly or inadequately mitigated risks during the time between notification and identification and remediation by NICNAS through post-market activities.

On the other hand, the reduction in unnecessary regulatory costs for new chemicals has the potential to lead to improvements in public health, and worker and environmental outcomes, if industry replaces more hazardous existing chemicals with safer alternatives (industry has anecdotally reported that this may be a consequence if the pre-market costs are reduced).

This approach could also lead to an increase in the range and type of chemicals introduced into, and used in, Australia. This may be contrary to the objectives of some consumer and environmental groups committed to reducing the use of industrial chemicals in Australia.

In addition:

- the reliance on self-assessment for new chemicals will decrease the level of information NICNAS possesses on the use and introduction of chemicals. Environmental and community stakeholders are concerned about the lack of information available on chemicals in use in Australia;

- the capacity for industry to introduce any chemical that has been approved by another recognised country would continue to concern environmental stakeholders. Greater use of international assessment data and reports without regard to there being different conditions in Australia, may cause more damage than would occur in another country. This is due to two key reasons: Australia has relatively less sophisticated environmental disposal infrastructure (i.e. sewerage systems and incinerators) than other first world countries; and the distinctiveness of Australia's aquatic environment. Australia's waterways have a tendency to regularly flood, which means that chemicals that may be present in the ground are liable to be widely dispersed by a flooding event;
- if requirements for new chemicals were reduced, NICNAS would be able to invest more of its resources on post-market monitoring and assessing the use of existing chemicals that may pose a higher risk. A less prescriptive process for assessment of these chemicals, with the option of targeted existing chemical assessments, would allow flexibility to tailor assessment requirements to the risks posed by an existing chemical; and
- a more comprehensive compliance regime combined with increased information gathering powers may provide assurance that NICNAS is better equipped to manage non-compliance, and that industry is compliant with the legislative requirements. While this has the potential to increase consumer confidence in the regulatory system, this confidence would depend on the extent to which consumers perceive that: industry is complying with the requirements; and NICNAS is willing and able to take action in the event that post-market monitoring reveals concerns. Alternatively, a focus on post-market efforts may reinforce a perception that 'the horse has already bolted' if NICNAS identifies a concern after the chemical has been brought to market.

Industry

Reducing NICNAS' role in pre-market restrictions (that is, by expanding the classes of chemicals that are exempt or may be introduced following notification and reducing pre-market assessment by NICNAS) would be expected to:

- reduce costs to industry¹². This would result in a reduction of regulatory fees for businesses introducing all but the highest risk chemicals. While the precise value of this saving is difficult to accurately determine, industry has also indicated that a reduction in the regulatory burden would be expected to encourage the introduction of chemicals previously considered not financially viable by industry. Industry stakeholders indicate that removal of such pre-market obligations is also

¹² Noting that there would be an initial increase in costs to industry as the result of industry needing to familiarize themselves with the new requirements. This impact is likely to be felt more strongly by smaller businesses.

likely to lead to the introduction of a greater number of new chemicals including safer, more modern and cost-effective chemical substitutes, increased competition and increased chemical innovation;

- reduce the time taken to get new products to market; and
- improve planning opportunities and opportunities for improved business efficiencies. Reduced delays may provide businesses with a first mover advantage, through early introduction of a new product to the market and help to remove any non-financial barriers to the introduction of new chemicals.

While Option 2 could result in decreased regulatory requirements being imposed by NICNAS on businesses prior to the introduction of the chemical, there would be a corresponding increase in post-market costs associated with NICNAS' post-market monitoring and annual reporting obligations. Further:

- it is feasible that other government departments may expand their roles, or businesses themselves will perform risk management activities in the absence of NICNAS pre-market assessment of some chemicals due to general duties of care under workplace safety, consumer protection, or other legislation; and
- there would be a compliance cost to industry if NICNAS' mandatory information-gathering powers are extended. The extent of this impact would depend on the frequency of NICNAS' information requests to industry.

If consumer confidence in the regulatory regime decreases (for the reasons described in relation to the analysis of the impact of Option 2 on consumers) this may have an adverse impact on industry that relies on consumer support and a 'social mandate' for the use of chemicals in Australia.

NICNAS

A preliminary estimate by the Department of Health and Ageing is that initial implementation of this option to establish the new arrangements, potentially including IT systems, may require \$X m over four years. Further analysis would be required to establish the justification for any such increase in resources. Ongoing implementation will not require greater resources, or greater costs to government, but instead will affect how existing resources are allocated. The reduction in the NICNAS pre-market assessment role will necessarily change the focus of resourcing within the organisation. As this option aims to rebalance NICNAS' regulatory effort, through a focus on post-market monitoring and enforcement, there will be greater regulatory effort directed to chemicals already on the market. This change of approach would also have an internal impact on NICNAS' organisational structure and on the focus of its staff.

Expanding and strengthening NICNAS' regulatory tools will likely result in stronger and improved decision-making. Greater information gathering powers and

enforcement tools will enable decisions made through the scheme administered by NICNAS to be better informed and validated.

A graduated and effective mix of compliance provisions will strengthen NICNAS' ability to enforce compliance with legislative requirements. With a broader set of tools and suite of powers available, NICNAS will be able to better align the severity of the offence with an enforcement action. With more tools available, NICNAS will have the power to enforce a matched penalty for non-compliance. Increased compliance monitoring may also result in a reduction and prevention of chemical misuse. The increased efficiency provided by a range of formal compliance tools (as opposed to current informal methods of enforcement) will redistribute current resources and allow NICNAS to target its compliance and enforcement activities to areas that pose the greatest risk to human health, the public and the environment.

Other risk management agencies

This option increases the focus on other risk management agencies because NICNAS will retain no residual risk management functions. As noted previously, NICNAS currently issues permits and certificates, a percentage of which include limitations on use. Under this option, most of these chemicals would be able to come straight to market without the need for pre-market assessment (nor the issue of a certificate or permit). This would reduce the information available to risk management agencies and limit their ability to determine the need for regulatory controls.

For the small class of chemicals that pose much higher risk and will continue to be assessed by NICNAS, other risk management agencies will be solely responsible for the imposition of any limitations on use.

Option 3: Graduated, risk based approach with pre and post-market emphasis based on risk profile of chemicals

In summary, this option involves NICNAS adopting a graduated, risk-based approach to the regulation of industrial chemicals such that the level of regulatory intervention (either pre-market or post-market) matches the anticipated level of risk posed by the industrial chemical and its use. Under this option there would be four classes of industrial chemicals, each with different pre and post-market requirements.

Community

In relation to chemicals falling within Classes 1-3 (no pre-market assessment):

- industry stakeholders have advised that the reduction in time delays for the introduction of lower risk chemicals will likely result in the introduction of newer and safer chemicals. This could lead to public health, worker and environmental benefits, if these chemicals are introduced and subsequently replace more hazardous existing chemicals. As the number of chemicals able to be introduced

through Classes 1-3 would be fewer than those able to be introduced under Option 2 (but greater than can currently be introduced through Option 1), this benefit is likely to be greater than for Option 1 but not as significant as for Option 2; and

- consumer confidence in the system will depend on the regulations striking the right risk-based balance in terms of those chemicals able to be introduced through Classes 1-3 (i.e. those chemicals not requiring pre-market assessment).

In relation to Class 4 chemicals that would continue to require pre-market assessment by NICNAS:

- this option assures consumers that medium and higher risk chemicals will continue to be subject to pre-market assessment by NICNAS. This is therefore likely to provide a greater level of public confidence than Option 2;
- providing NICNAS with the ability to impose limitations on a certificate will provide an increase in the protection of public health, workers and the environment in the limited circumstances where the risk cannot otherwise be appropriately managed;
- similarly, providing NICNAS with the ability to refuse a certificate or to not include a chemical on AICS will provide an increase in the protection of public health, workers and the environment and minimise the existing regulatory gaps described in relation to Option 1.

In relation to existing chemicals, if requirements for new chemicals were reduced, NICNAS would potentially be able to invest more of its resources on post-market monitoring and assessing the use of existing chemicals that may pose a higher risk. A less prescriptive process for PECs (with targeted existing chemical assessments) would allow flexibility to tailor assessment requirements to the risks posed by an existing chemical.

A more comprehensive compliance regime combined with increased information gathering powers would provide assurance that NICNAS is better equipped to manage non-compliance. This, in turn, is likely to increase the public's confidence in the regulatory system.

Industry

A realignment of the regulatory effort toward chemicals with higher risk profiles would improve the efficiency and effectiveness of the NICNAS processes.

This would be intended to result in greater regulatory focus on existing chemicals and higher risk chemicals and a reduction in the costs for industry associated with the introduction of lower risk chemicals.

In relation to chemicals falling within Classes 1-3 (no pre-market assessment), the impacts on industry are expected to include the following:

- The expansion of chemicals falling within these classes would decrease the number of low volume/ low risk chemicals requiring pre-market assessment and the cost of effort in the preparation of assessment material. The re-alignment of classes (and the expansion of those chemicals falling into Class 2 and 3) would be expected to reduce permit and certificate assessments by up to 31 per cent¹³.
- The changes would be expected to improve the time taken to get new products to market, reducing elapsed time cost down by 14 - 90 days dependent on the previous assessment timeframes (see table 1-1).
- For companies there will also be improved planning opportunities and business efficiencies. Reduced delays may provide businesses with a first mover advantage through early introduction of a new product to the market, and help to remove any non-financial barriers to the introduction of new chemicals.
- The reduction in unnecessary regulatory requirements may also encourage the introduction of chemicals previously considered not financially viable by industry. Industry stakeholders indicate that rebalancing of the regulatory effort is also likely to lead to the introduction of a greater number of new chemicals including safer, modern and cost-effective chemical substitutes, increased competition and increased chemical innovation.
- Greater alignment with international regulatory arrangements (for Classes 1-3) may contribute to the Australian industry's ability to compete in the global marketplace to the extent to which chemicals are an input to Australian exports and import competing industries. Greater alignment between such aspects of chemical notification as data requirements, exemptions and volumes in Australia and internationally may also assist in simplifying the notification processes.

While these impacts represent a significant improvement on Option 1 (the status quo) these benefits to industry are not likely to be as significant as for Option 2 where even more chemicals are eligible for automatic entry or notification only (including all chemicals that have been approved by a recognized country).

In relation to Class 4 chemicals that would continue to require pre-market assessment by NICNAS, the impacts on industry are expected to include the following:

- Streamlined assessment processes and better alignment of data requirements with those of comparable countries is likely to decrease the cost to industry of preparing applications for assessment. In addition, chemicals which are

¹³ Comparison by NICNAS of those chemicals assessments, both permits and certificates, undertaken during a two year period 2010-12.

determined to be potentially of low risk will have shorter assessment periods. This is estimated to be at least 35% of all permit and certificate assessments.¹⁴

- Allowing NICNAS, in consultation with other risk management agencies, to include limitations on a certificate provides NICNAS with the ability to apply measures commensurate with the risks posed by the chemical. There is potential for some chemicals to present a significant risk, such that limitations should be in place at the time of introduction (this includes some chemicals that are currently subject to NICNAS permits and currently contain limitations on use). These circumstances could be expected to occur in limited situations with approximately 17% of all permit and certificate assessments to include limitations that could not be applied by risk management agencies. Few businesses are likely to be impacted due to the very limited circumstances where risks could not be adequately addressed through existing risk management agency approaches.
- Allowing NICNAS, in consultation with government risk management agencies, to refuse a certificate or not enter a chemical onto AICS, or to remove a chemical from AICS, provides NICNAS with the regulatory capability to apply measures commensurate with the risks posed by the chemical.
- This option would, in some cases, allow for commercial confidential and other information collected by NICNAS to be provided to government risk management agencies for the purposes of protecting public, worker and environmental safety. In terms of impact on industry, it is likely that the transfer of this information will increase the risk of inappropriate or unintentional disclosure (due to a greater number of people having access to the information), however, this risk could be managed as it currently is with respect to agricultural and veterinary chemicals. Appropriate provisions are envisaged to ensure confidentiality is maintained by the receiving agencies, with penalties for inappropriate release or use of the information. Therefore, the impact of this is likely to be minimal for industry.
- Industry will likely see increased benefits of the flow of information between regulatory agencies. The availability of this information reduces the likelihood of overly conservative decision-making by both NICNAS and government risk management agencies and thus may alleviate the instances of unnecessary restrictions on industry.

In relation to existing chemicals:

- Expanding NICNAS' risk management functions to include particulars and limitations on use on certificates and/or AICS, where necessary, will clarify secondary notification expectations, resulting in greater efficiency and effectiveness. With clearer expectations, it is likely that industry will better understand the circumstances that require a secondary notification, and therefore it

¹⁴ Based on the number of PLCs as a percentage of all permits and certificates, undertaken during a two year period 2010-12

is expected that a greater number of businesses will conduct a secondary notification. This may represent an increase in regulatory activity for businesses that have not previously understood the process and consequently either unintentionally or intentionally opted not to perform them; however this increase would be associated with current obligations.

- An improved existing chemicals assessment process will reduce delays in finalising assessments and provide increased regulatory certainty. There would be a compliance cost to industry if NICNAS' mandatory information-gathering powers are extended, but the extent of this impact would depend on the frequency with which NICNAS would make such requests.

In relation to post-market monitoring and enforcement, a graduated and effective mix of compliance provisions will strengthen NICNAS' ability to enforce compliance with legislative requirements. With a broader set of tools and suite of powers available, NICNAS will be able to better align the severity of the offence with an enforcement action and to target its compliance and enforcement activities to areas that pose the greatest risk to human health, the public and the environment.

Expanding NICNAS' risks management functions to include the monitoring and enforcement of limitations on use on certificates and/or AICS will represent an increase in the regulatory activity for a small number of businesses however this is expected to be minimal given current compliance with permit conditions and the voluntary adoption by industry of NICNAS risk recommendations.

As for all reform options (Options 2-5), there is likely be an initial increase in costs to industry as the result of industry stakeholders needing to familiarize themselves with the new requirements. This impact is likely to be felt more strongly by smaller businesses.

NICNAS

A preliminary estimate by the Department of Health and Ageing is that initial implementation of this option to establish the new arrangements, potentially including IT systems, may require **\$X m** over four years. Further analysis would be required to establish the justification for any such increase in resources.

As for Option 2:

- This option will not require greater ongoing resources or impose greater costs to government, but instead will affect how existing resources are allocated. The reduction in the NICNAS pre-market assessment role will necessarily change the focus of resourcing within the organisation. This change of approach would also have an impact on NICNAS' organisational structure and on the focus of its staff.
- Expanding and strengthening NICNAS' regulatory tools will likely result in stronger and improved decision-making. Greater information gathering powers

and enforcement tools will enable decisions made by NICNAS to be better informed and validated.

- A graduated and effective mix of compliance provisions will strengthen NICNAS' ability to enforce compliance with legislative requirements. With a broader set of tools and suite of powers available, NICNAS will be able to better align the severity of the offence with an enforcement action. With more tools available, NICNAS will have the power to enforce a matched penalty for non-compliance. Increased compliance will likely result in a reduction and prevention of chemical misuse allowing NICNAS to target its compliance and enforcement activities to areas that pose the greatest risk to human health and the environment.

Other risk management agencies

The main impact of this option on other risk management agencies is that the level of engagement between NICNAS and other risk management agencies may increase.

As described in more detail at Attachment B, in most cases NICNAS will continue to undertake risk assessments and make recommendations to risk management agencies. This has no additional impact on risk management agencies by comparison to the status quo (Option 1). Where there will be a change, it is proposed that NICNAS would consult risk management agencies before deciding to impose any limitations on use (because the risk cannot otherwise be managed) and before refusing to issue any certificate or refusing an entry on AICS (on the basis that risk cannot be managed). In these limited circumstances there may be small resource implications for other risk management agencies.

Option 4: As for Option 3 but with responsibility for imposition of post-market obligations resting with existing risk management agencies

Community

This option would be expected to have most of the same impacts on the community as Option 3.

The key difference is that under this option sections of the community would continue to be concerned that there are gaps in regulatory coverage and that once NICNAS has undertaken a risk assessment of a higher risk new industrial chemical, the chemical could be introduced before risk management agencies have imposed any necessary risk management conditions. There would also continue to be circumstances where there is no relevant risk management agency, and hence no regulatory authority to impose any limitations on use that are necessary to manage risk.

As assessed chemicals are generally higher risk (because the chemical would not have been assessed by NICNAS if it was not higher risk given that lower risk chemicals

will fall within Classes 1-3 and not subject to NICNAS assessment), this approach has potential to undermine confidence in the risk-based nature of the regulation.

This option also depends on community confidence in industry voluntarily complying with any risk management recommendations, prior to their consideration and implementation by risk management agencies.

Industry

This option would be expected to have most of the same impacts on industry as Option 3.

The key difference is that NICNAS could not impose any limitations on the use of any new industrial chemical regardless of the risks identified during assessment and regardless of whether or not there was an existing risk manager able to impose appropriate limitations on use.

This may create uncertainty if industry complies with the risk management recommendations of NICNAS (limitation or conditions on use), but then different conditions or limitations are imposed by the relevant risk management agency. This impact would not exist if industry did not choose to voluntarily comply with the recommendations, however this would likely lead to a reduction in consumer confidence which has flow-on effects to industry.

NICNAS

As for Options 2 and 3, this option will not require greater ongoing resources or impose greater costs on government but instead will affect how existing resources are allocated. A preliminary estimate by the Department of Health and Ageing is that initial implementation of this option to establish the new arrangements, potentially including IT systems, may require **\$X m** over four years. Further analysis would be required to establish the justification for any such increase in resources.

Other risk management agencies

It is likely that there will be more circumstances in which NICNAS would make recommendations with resultant impacts for other risk management agencies.

If there is no relevant risk management agency, the matter would be referred to a risk management agency agreed by all States and Territories, following a period of negotiation. The determination of the agency tasked with addressing risks that do not align with existing structures will likely be time consuming and would also generate uncertainty.

Agencies tasked with addressing such risks may also face increased costs associated with the development and implementation of necessary practical controls outside of their existing regulatory frameworks.

Option 5: Pre-market emphasis on regulation

In summary, this option significantly reduces the number of chemicals exempt from regulation or subject only to notification to NICNAS, with the default position being assessment by NICNAS. Efficiency is gained through reducing NICNAS' risk assessment processes following notification. Post-market monitoring and enforcement activity would be increased.

Community

This option represents a more conservative approach to the regulation of industrial chemicals and it could therefore be argued that there is less risk of any incorrectly or inadequately mitigated risks arising from self-assessment of new chemicals or the automatic introduction into Australia of chemicals approved by other comparable countries. In addition, with NICNAS assessing all new chemicals there would be greater information available to risk management agencies. It is likely that relative to other options this would minimize any potential negative impacts of industrial chemicals on public health or the environment.

However, this approach could also lead to a decrease in the range and type of chemicals introduced into, and used in, Australia (because the pre-market assessment process is more costly and time intensive to industry, and therefore discourages introduction of new chemicals). This could have benefits for consumers and the environment, or may mean that more hazardous chemicals remain in circulation for a longer period (because they are not replaced with safer alternatives, as noted by industry stakeholders).

The increased level of information NICNAS possesses on the use and introduction of chemicals, along with more comprehensive compliance regime and increased information gathering powers, is likely to increase the public's confidence in the regulatory system.

Industry

By increasing the pre-market restrictions (that is, by expanding the classes of chemicals that must be subject to pre-market assessment by NICNAS) this would be expected to:

- increase costs to industry;
- increase the time taken to get new products to market; and
- reduce planning opportunities and opportunities for improved business efficiencies. Delays to market may reduce any first mover advantage through

early introduction of a new product to the market and increase non-financial barriers to the introduction of new chemicals.

Gains made through the streamlining of the assessment process will principally affect those businesses introducing industrial chemicals that would have been assessed under the current permit or assessment certificate framework.

While Option 5 could result in increased regulatory requirements on businesses being imposed by NICNAS prior to the introduction of a chemical, there would be a corresponding decrease in NICNAS post-market monitoring.

If this Option leads to increased consumer confidence in the regulatory regime this may have some positive impact on industry.

NICNAS

As for Options 2, 3 and 4, this option will not require greater ongoing resources or impose greater costs to government but instead will affect how existing resources are allocated. A preliminary estimate by the Department of Health and Ageing is that initial implementation of this option to establish the new arrangements, potentially including IT systems, may require **\$X m** over four years. Further analysis would be required to establish the justification for any such increase in resources.

Other risk management agencies

This option is not expected to have any significant impact on existing risk management agencies.

Part H: Consultation

Consultations

Stakeholder engagement workshops were held in Canberra (25 June 2012), Melbourne (27 June 2012), Sydney (29 June 2012) and Brisbane (10 July 2012).

Workshops were attended by stakeholders from: State and Federal Government departments, industry associations, and from industry and union sectors. No stakeholders from environmental or public health organisations were in attendance at the meetings.

The workshops were an opportunity for stakeholders to provide comments and feedback on the problem identification and options in the Discussion Paper that was jointly released by the Department of Health and Ageing and the Department of Finance and Deregulation in June 2012.

Following the June 2012 workshops, there has been follow up interviews with individual business representatives and public and environmental health professionals, as well as presentation of early findings to community, environment, industry association and industry stakeholders.

A further workshop was held in Melbourne on 15 October 2012 and was attended by stakeholders from the industry associations, industry, unions and environmental and public health organisations. The workshop was an opportunity for stakeholders to further comment on the potential impact of possible reform options.

[Description of June/July 2013 consultations]

Outcome of consultations

The options proposed in this RIS reflect the diverse views held by stakeholders.

On the one hand, most industry stakeholders supported:

- reducing pre-market controls to enable more timely and less costly access to market;
- the automatic acceptance in Australia of approvals from comparable countries;
- the streamlining of existing NICNAS assessment processes; and
- NICNAS focusing on risk assessment rather than risk management, specifically that NICNAS should not be able to impose limitations on use of new or existing chemicals, but should instead make recommendations to other risk management

agencies who may consider and, where appropriate, implement any risk management conditions.

On the other hand, most consumer, public health and environmental groups:

- expressed concern 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 management agency, or there is a delay in the risk management agency considering the NICNAS recommendations and imposing any necessary conditions for safe use; and
- NICNAS should have the power to impose conditions, restrict or ban chemicals.

These views have informed the options presented in this RIS.

A number of issues were also 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 (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;
- the lack of flexibility for NICNAS to deal with chemicals introduced in low concentrations, such as fuel additives; and
- the limited ability of NICNAS to undertake urgent assessments or re-assessments in response to issues of immediate concern.

Again, these issues are proposed to be addressed through:

- the various options presented; and
- the proposed new streamlined assessment process which would be applicable as part of Options 2-5. One of the main differences between the options is the volume of assessments undertaken by NICNAS (with the lowest volume of assessments under Option 2 and the highest under Option 5). Regardless of how

many assessments are undertaken by NICNAS, it is broadly recognised that there is a need to streamline the assessment process. The proposed streamlined approach to assessments is described at Attachment B.

In terms of 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 AICS.

While it was acknowledged that a new assessment and prioritisation framework was introduced on 1 July 2012 (which will enable the screening and assessment of 3,000 chemicals over 4 years) it was also noted that:

- the PEC assessment process is rigid and resource intensive and does not provide for adequate flexibility to provide more targeted assessment and rapid response; and
- there is a lack of data available for NICNAS to identify appropriate priority existing chemicals and an inability to identify which of the chemicals on AICS are not in use.

Again it is proposed that a streamlined existing chemicals assessment process could form part of all of the options (other than Option 1 which retains the status quo).

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; and
- the absence of any mandatory system of adverse reporting.

These issues are also proposed to be addressed as part of Options 2-5, and are discussed in more detail in Attachment B.

Part I: Conclusion and recommended option

As reflected in the previous Part, stakeholders hold diverse views. In essence, one group of stakeholders is seeking a more conservative, precautionary approach to the regulation of industrial chemicals (focusing on pre-market assessment – Option 5) and another group is seeking a less conservative approach with a shift away from pre-market assessment to post-market monitoring (Option 2).

Both perspectives are based on a logical argument, and different stakeholders presented different evidence as to why their preferred approach was desirable.

Taking into account the views of all stakeholders, it is considered that Option 3 is the preferred option.

Compared to the other options, this Option:

- strikes a balance between pre-market and post-market controls, based on the presumed risk posed by the chemical. A well-balanced framework will ensure that barriers to market entry will be minimised, regulatory efficiencies will be achieved, and risks to public health and the environment will be appropriately managed;
- a realignment of the regulatory effort toward chemicals with higher risk profiles will improve the efficiency and effectiveness of the NICNAS processes. This is intended to result in greater regulatory focus on existing chemicals and high risk chemicals, and a reduction in the costs for industry associated with the introduction of new, safer chemicals;
- ensures a greater alignment with international regulatory arrangements (i.e. through the criteria for Classes 1-3) but does not mean that international assessments are automatically accepted for higher risk chemicals. This balances the need to encourage Australian competitiveness with the desire to ensure that Australia is still able to consider (for chemicals subject to assessment) any risks that are specific to the Australian context; and
- allows NICNAS, in consultation with government risk management agencies, to include limitations on a certificate or on AICS in order to fill an existing regulatory gap. This provides NICNAS with greater regulatory capability to apply and, where no other risk manager exists, enforce measures commensurate with the risks posed by the chemical. There is potential for some chemicals to present a significant risk, such that limitations should be in place at the time of introduction.

Other proposed reforms, for example to streamline the assessment process for both new and existing chemicals, are also expected to reduce inefficiency, improve the timeliness of assessments and reduce cost to industry.

Part J: Implementation and Review

Implementation

In order to realise the benefits described in the options, it is imperative that implementation be conducted appropriately. Should Government agree the preferred option, it is proposed that:

- further work be undertaken on mapping out the detail of Option 3 (the preferred option) (July - August 2013);
- further consultation be undertaken on the detail that will be used to inform the development of drafting instructions for amendments to the ICNA legislation and the development of delegated legislation (Regulations and Guidelines) (October 2013 – February 2014);
- the amending legislation be introduced into Parliament during the 2014 Autumn sitting period;
- subject to Parliamentary passage of the necessary legislative changes in mid to late 2014, the proposed changes take effect from 1 July 2015; and
- during 2014, delegated legislation will need to be developed to support the changes reflected in the Act. This will include the development of revised fee arrangements to align with the new regulatory framework. The new fees will be subject to a Cost Recovery Impact Statement (CRIS). It is anticipated that, if the primary legislation is passed in 2014, consultation on the proposed fees and CRIS could occur by end 2014 to enable the new fees arrangements to be reflected in delegated legislation and to take effect from 1 July 2015.

This implementation timeframe will provide sufficient time for:

- NICNAS to make changes to systems to reflect the new processes;
- NICNAS to update guidance materials to reflect the changes;
- industry to become acquainted with new requirements; and
- broadly based stakeholder education to occur.

In parallel with the development of the legislation, and all supporting systems changes, it is proposed that a detailed evaluation plan be developed.

The plan should be implemented from January 2015 (prior to introduction of the reforms on 1 July 2015) when baseline information could be collected to enable comparison at the completion of the evaluation and review period.

Review

It is proposed that the reforms should be reviewed within 5 years of the full legislative change coming into effect. This should be a reasonable amount of time, following change, to allow impacts to be assessed.

Benefits realisation could be measured, against the base case data collected as part of the evaluation process, which will commence in January 2015 (as discussed above).

The key focus of the review will be ensuring that:

- the problems identified in this RIS have been addressed;
- the objectives of Government have been achieved;
- any unintended consequences have been addressed or are able to be addressed;
and
- any necessary further reforms to achieve Government objectives (including any new objectives) continue to be addressed.

Attachment A - Current state impact analysis: NICNAS Processes

Pre-market impacts

Pre-market activities are those that industry is required to comply with prior to being granted permission to bring new chemicals into Australia. For the purposes of this RIS, pre-market activities include registering with NICNAS, notifying NICNAS and applying for chemical assessments.

Registering with NICNAS

In 2011, approximately 600¹⁵ new companies wishing to import and/or manufacture industrial chemicals for commercial purposes registered with NICNAS for the first time with a further 4300¹³ existing registrants renewing their registration.

The registration process typically includes the following steps:

- establishing whether a business is required to register;
- establishing the tier level for the business; and
- making an application - applications must contain an approved form completed in full and be accompanied by the required payment.

Applications for registration are considered as soon as practicable within 30 days of their receipt. Once the application has been processed, the registrant is allocated a registration number and issued with a certificate of registration. The introducer's name is placed on the Register of Industrial Chemical Introducers.

Applying for a chemical assessment

Once registered, companies wishing to introduce industrial chemicals may need to complete certain pre-market regulatory activities. The following categories of pre-market regulatory activity have been identified:

- standard and limited assessments (certificate);
- polymer of low concern and self assessed polymers of low concern (certificate); and
- permit applications.

¹⁵ NICNAS, [NICNAS Annual Report 2010-11](http://www.nicnas.gov.au/publications/Annual_Reports/Annual_Report_2010_2011_Online/default.asp), Canberra 2011. Online reference: (www.nicnas.gov.au/publications/Annual_Reports/Annual_Report_2010_2011_Online/default.asp)

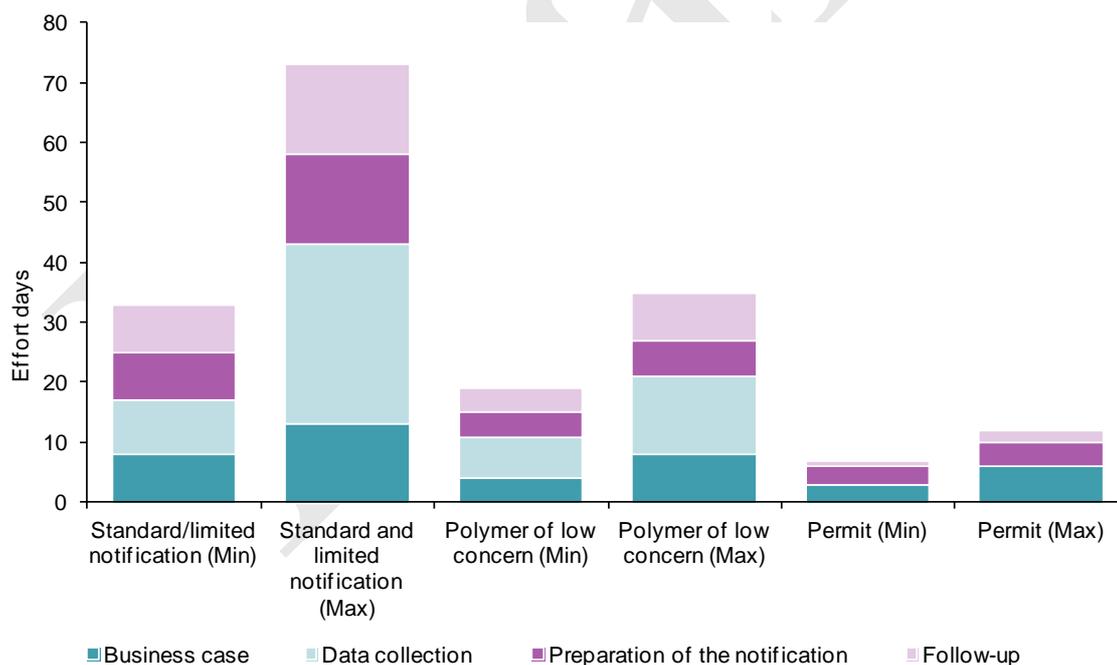
Combined, the activities above accounted for 266 of NICNAS' 287 notification and assessment applications in 2010-11.

Regardless of the type of pre-market activity, businesses consulted indicated that their internal regulatory costs were driven by undertaking the following activities:

- developing a business case to understand if market opportunities justified the regulatory costs;
- collecting the necessary data to substantiate the application;
- developing the necessary paperwork for NICNAS;
- addressing any follow-up questions from NICNAS in relation to the application.

The following figure, identified by industry stakeholders in interviews with KPMG, shows the distribution of effort days for the three pre-market regulatory activities costed. Maximum and minimum are shown to highlight the range of impacts the activities have, depending on the nature of the application.

Figure A -1: Distribution of effort days to complete pre-market regulatory activities



Source: Targeted industry consultation

Using benchmark industry wages, accounting for the use of consultants that assist businesses prepare the applications and including the NICNAS fee, the total unit cost for each regulatory activity can be estimated as set out in Table A-1 below.

Table A -1: Estimated unit costs (based on targeted industry consultation)¹⁶¹⁷

Regulatory cost	Standard/limited assessment (certificate)	Polymer of low concern assessment (certificate)	Permit
Cost of effort (total effort days)	Min: \$19,000 (33) Max: \$41,000 (73)	Min: \$11,000 (19) Max: \$20,000 (35)	Min: \$4,000 (7) Max: \$7,000 (12)
Industry consultant	Min: \$4,000 Max: \$10,000	Min: \$3,000 Max: \$7,000	Min: \$3,000 Max: \$7,000
NICNAS fee	Min: \$12,000 ¹⁸ Max: \$16,800 ¹⁹	Min: \$5,600 Max: \$5,600	Min: \$4,000 Max: \$4,000
Estimated unit cost	Min: \$34,000 Max: \$67,800	Min: \$19,600 Max: \$32,600	Min: \$11,000 Max: \$18,000

One important issue consistently raised in the context of preparing information for NICNAS, was the use of international data and evidence of the risks associated with a chemical. Industry stakeholders suggest this is particularly relevant, when a chemical has been subject to contemporary evaluation in jurisdictions such as Europe and/or North America. In many of the cases cited during stakeholder consultations, the cost associated with commissioning new tests was sufficient to result in the company either not proceeding with, or withdrawing from a notification process.

Consultation with industry has also provided evidence to suggest that the impacts of existing NICNAS processes go beyond the quantified costs outlined above. These include the:

- impact of the elapsed time associated with receiving NICNAS approval;
- reformulation costs associated with changing a chemical compound in response to (or in anticipation of) NICNAS' regulatory approvals processes; and
- opportunity costs associated with lost sales. Industry stakeholders have suggested that, due to the complex and costly nature of the regulatory approvals, they may avoid bringing the chemical into Australia.

These costs are also discussed in the body of the RIS (refer discussion of the impacts of Option 1 – base case)

¹⁶ Source: Identified by industry stakeholders during interviews undertaken by KPMG in 2012.

¹⁷ If you are accessing this document using a screen reader and having difficulty reading the table data, please contact our the NICNAS Review Team on email NICNAS.review@health.gov.au.

¹⁸ Limited notification assessment fee.

¹⁹ Standard notification assessment fee

Impact of elapsed time

Industry consultation explored the number of elapsed days associated with each regulatory assessment or event. Most businesses consulted indicated that the total elapsed time taken to complete a regulatory assessment was just as important as the number of business days taken to prepare the information. From a business perspective, the total elapsed time includes all the steps associated with preparing the necessary paperwork and the time taken by NICNAS to assess the proposal.

The following table compares the total elapsed time for each regulatory assessment or event. The table highlights that the statutory timeframes for an assessment represent between approximately 25 and 45 per cent of the elapsed time allowed by businesses for standard/limited notifications and permits, while PLCs appear to occur within their statutory timeframe for elapsed time as well.

Table A -2: Time taken to prepare and assess notifications and permits²⁰²¹

Regulatory cost	Standard/limited notification	Polymer of low concern	Permit
Total effort days (as outlined above)	Min: 33 Max: 73	Min: 19 Max: 35	Min: 7 Max: 12
Estimated elapsed days	Min: 187 Max: 200	Min: 73 Max: 80	Min: 73 Max: 80
NICNAS' statutory assessment timeframe	Min: - Max: 90	Min: - Max: 90	Min: 14 Max: 28

The reported consequences of the elapsed time taken for businesses and NICNAS to achieve the regulatory approval, even where statutory timeframes are met, included missing product launch dates and loss of sales and market share.

Early introduction permits (EIPs) are available for assessments under STD, LTD and PLC categories. The statutory timeframe for an EIP is 28 days and there is no fee for EIPs for non-hazardous chemicals or PLCs. In 2011-12 99 EIPs were published, of which 81 were free.

²⁰ Source: Identified by industry stakeholders in interviews undertaken by KPMG in 2012.

²¹ If you are accessing this document using a screen reader and having difficulty reading the table data, please contact our the NICNAS Review Team on email NICNAS.review@health.gov.au.

Reformulation costs

Industry has reported that in anticipation of, or in response to, NICNAS' conditions, products are reformulated.

Opportunity costs

For some businesses the direct and indirect costs described above means that a project will not proceed. While regulatory costs are an important business consideration, other costs and market conditions will clearly play an important role in determining what chemicals a company elects to import into Australia - as PACIA notes, Australia represents 0.6% of world sales for chemicals.²²

While widely cited as a consequence of the regulatory scheme administered by NICNAS, understanding the frequency and impact of the opportunity costs is difficult. For companies that maintain a register of their foregone opportunities, there is an understandable reluctance to provide or discuss commercially sensitive information in a public forum.

That said, the PACIA submission cites a company that had an opportunity to submit six notifications in Australia in the past 18 months.

Post-market impacts

Post-market impacts are those experienced after a chemical is approved for use in Australia. In this context, post-market impacts will include any regulatory reporting requirements imposed on businesses as well as the impacts of any conditions of use imposed directly by NICNAS. The post-market impacts explored in this RIS include secondary notifications and annual reporting against exemptions.

Secondary notifications

For chemicals that have been previously assessed by NICNAS, the ICNA Act imposes certain post-market obligations on introducers. Firstly, 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). The current problems associated with the secondary notification process include that 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).

²² PACIA, NICNAS Review Submission, 10 August, 2012

The main reason why the function or use of the chemical cannot be stated on the AICS entry is due to confidentiality provisions in the ICNA Act that allow notifying companies to claim chemical name, function and use as confidential information. The result of this is that it can be difficult for introducers to know whether secondary notification obligations apply to them and the assessment process (following secondary notification) can be unnecessarily cumbersome.

While industry has provided evidence of problems associated with the secondary notification process, NICNAS completed four secondary notification assessments in 2011-12. Such a low volume of secondary notifications suggests that there are opportunities to improve the efficiency and effectiveness of the secondary notification process.

Annual reporting

NICNAS also 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.

Targeted consultation with businesses suggested that the administrative cost to prepare the annual reports varies significantly. Businesses that have invested in more comprehensive inventory management systems report lower annual reporting costs.

Table A-3: Estimated time taken to prepare annual reports²³²⁴

Preparation of annual reports	Time (days)
Estimated days	Min: 5 Max: 9
Estimated unit of annual reporting	Min: \$3,000 Max: \$5,000

²³ Source: Identified by industry stakeholders in interviews undertaken by KPMG in 2012.

²⁴ If you are accessing this document using a screen reader and having difficulty reading the table data, please contact our the NICNAS Review Team on email NICNAS.review@health.gov.au.

Attachment B - Detailed information regarding Option 3

B1. The role of NICNAS under Option 3

NICNAS' primary role would continue to be the undertaking of risk assessments of industrial chemicals (as currently defined in the *Industrial Chemicals (Notification and Assessment) Act 1989*), and providing information to risk management agencies and other stakeholders. This would enable risk management agencies to manage residual risk, in accordance with their own standards or regulatory schemes.

NICNAS would, however, maintain some risk management functions, consistent with its current functions. This means that the NICNAS regulatory framework must:

- describe the classes of chemicals that would be: beyond the scope of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act); afforded automatic market entry provided certain criteria are met; subject to notification to NICNAS only; and subject to risk assessment by NICNAS;
- distinguish between those chemicals that would be subject to NICNAS controls (such as those chemicals that are currently subject to controls under a NICNAS permit) and those chemicals that would be subject only to controls imposed by other risk management agencies (if any); and
- strike a balance between pre-market and post-market controls, based on the potential risk posed by the chemical. A well-balanced framework would ensure that barriers to market entry would be minimised, regulatory efficiencies would be achieved, and risks to public health and the environment would be appropriately managed.

B2. Classes of new industrial chemicals

Currently, the NICNAS framework includes a complex web of notification and assessment arrangements for different types of chemicals. As this framework is not entirely risk based, some anomalies exist between chemicals subject to different levels of regulation.

It is proposed that NICNAS more fully adopt a graduated, risk-based approach to the regulation of industrial chemicals such that the level of regulatory intervention (either pre-market or post-market) matches the anticipated level of risk posed by the industrial chemical and its use.

Consistent with this approach, it is proposed that there be four classes of industrial chemicals described in the ICNA Act, each with different pre- and post-market requirements:

The following diagram summarises the proposed classes of industrial chemicals.

New Chemicals Framework

Indicative Risk	N/A	Very Low	Low	Medium / High or uncertain risk
Eligibility	Non-industrial chemicals	<ul style="list-style-type: none"> R&D <10 kg (not nanomaterials) Transshipment 	<ul style="list-style-type: none"> <1000 kg or <1% with no unreasonable risk (e.g., not nano, CMR, PBT) R&D nanomaterials <10 kg R&D site limited 	All other industrial chemicals
Pre-Market Process	Excluded	Auto Entry	Pre-Entry Notification Self-Assessment Against Criteria	Pre-Entry Assessment By NICNAS
Regulatory Outcome	None	Introduction Permitted	Introduction Permitted	When required <ul style="list-style-type: none"> NICNAS limits on introduction (e.g. volume, concentration, time, site, use limits) Risk management recommendations
Post-Market Process	None	None	Annual compliance declaration	Notifications
Safeguards	Policy forum – to resolve issues at interface	Feedback from State and Territory risk managers	<ul style="list-style-type: none"> Compliance audits and targeted post-market assessments Information exchange with risk managers Mandatory information gathering powers Enforcement offences 	<ul style="list-style-type: none"> Compliance audits and targeted post-market assessments Information exchange with risk managers Mandatory information gathering powers Enforcement offences

These classes are designed to:

- reduce the existing number of classes;
- ensure that the classes are based on the indicative risk of the chemical; and
- address anomalies in the current scheme by moving some chemicals that pose low risk into classes which demand less regulatory intervention.

Further detail about each of these classes is described below. For further information regarding the number of chemicals likely to fall within each of the classes, please refer to Attachment C.

Class 1 - Excluded uses of chemicals

<i>Indicative risk:</i>	Not applicable.
<i>Eligibility:</i>	As it currently does, the legislation would clarify that certain uses, in relation to industrial chemicals, would be excluded and not subject to the ICNA scheme because they are captured by other regulators.
<i>Pre-market process:</i>	Not applicable.
<i>Regulatory outcome:</i>	None by NICNAS.
<i>Post-market process:</i>	None by NICNAS.
<i>Safeguards:</i>	Existing policy forums would discuss issues at the interface.

Further detail:

It is proposed that the following classes of chemicals would continue to be excluded from NICNAS regulatory remit: chemicals for agricultural use; chemicals for veterinary use; chemicals for therapeutic use; and chemicals for use as a food or food additive.

As is currently the case, where a chemical is used for one of the above purposes and for an industrial use, it would continue to be subject to the NICNAS framework in relation to its industrial use.

In addition, the legislation would provide clarification about the treatment of:

- cosmetic products. Cosmetic products would not be regulated by NICNAS. NICNAS would continue to regulate the introduction of industrial chemicals for use in cosmetics.
- articles. While articles would not be regulated by NICNAS per se, chemicals that are released or leach from articles would continue to be regulated by NICNAS
- mixtures. As for articles, mixtures would not be regulated by NICNAS. But if NICNAS were assessing a specific industrial chemical and its proposed use was in a mixture, NICNAS would consider the industrial chemical in this context (including the influence of, and interaction between, the mixture and the chemical) where the methodology for doing so was available.

Class 2 - Chemicals in prescribed circumstances eligible for automatic market entry

<i>Indicative risk:</i>	This class contains chemicals that would be very low risk because of either the hazard characteristics of the chemical or the proposed use.
<i>Eligibility:</i>	Low risk chemicals (or low risk uses of chemicals) prescribed in regulations would fall within this class (see below for more detail).
<i>Pre-market process:</i>	Based on the low level of risk posed, this class of chemicals would not be subject to any pre-entry notification or assessment requirements.
<i>Regulatory outcome:</i>	Not applicable.
<i>Post-market process:</i>	Based on the low level of risk posed, this class of chemicals would not be subject to any post-market annual reporting requirements or audit by NICNAS. Effectively, the chemicals in the intended uses and volumes would be 'exempt' from the NICNAS pre- and post-marketing regime.
<i>Safeguards:</i>	State and Territory regulation of the use of these chemicals would continue to operate (for example, any work health and safety requirements). If any risks are identified by State and Territory regulators, it is expected that NICNAS would be notified, and the chemicals falling in this class could be reconsidered.

Further detail:

This class captures chemicals currently introduced through existing exemptions provided for the introduction of low volume, low risk chemicals.

Examples of chemicals that would fall within this class would be:

- new industrial chemicals used solely for the purpose of research, development or analysis and in a quantity of not more than 10 kilograms in any 12 month period (chemicals in this class exclude nanomaterials)
- new industrial chemicals, introduced at a port or an airport in Australia, that remain subject to the control of Customs and leave Australia less than 30 days after introduction (transhipment)
- such other chemicals prescribed in Regulations. The capacity to make regulations to describe other types of chemicals that fall within this class provides flexibility

into the future and enables movement of chemicals between classes, based on further information regarding risk.

Draft

Class 3 - Chemicals eligible for self-assessment and notification

Indicative risk: This class contains chemicals that would be relatively low risk because of either the hazard characteristics of the chemical or the proposed use.

Eligibility: This class would include all new industrial chemicals introduced in quantities less than 1,000 kilograms per year or less than 1% concentration provided that:

- the chemical does not pose unreasonable risk as judged against prescribed criteria that consider both the hazards of the chemical and the potential exposure to humans and the environment
- the chemical is not:
 - carcinogenic, mutagenic and reprotoxic (CMR)
 - persistent, bioaccumulative and toxic (PBT)
 - a nanomaterial that meets NICNAS' working definition (as is currently published on the NICNAS website)
 - prescribed in regulations as a chemical which may not be introduced under this Class.

Pre-market process: Introducers of these chemicals would self-assess against the description of the class in the legislation. If the introducer considers that the chemical they propose to introduce fits within this class they would notify NICNAS of their intention to introduce the chemical (pre-entry notification).

Post-market monitoring: Introducers would be required to submit an annual compliance declaration to NICNAS and NICNAS would 'audit' a proportion of the pre-market notifications annually.

Safeguards: The post-market reporting and auditing by NICNAS, information exchange with risk management agencies, information gathering powers and enforcement offences provide safeguards.

State and Territory regulation of the use of these chemicals would continue to operate (as described for Class 2).

Further detail:

The notification would include details about:

- the name by which the chemical is commonly known
- the proper chemical name (i.e. CAS or IUPAC name)
- CAS Number (where available)
- the proposed volume to be introduced
- the proposed use for the chemical
- confirmation that the chemical poses no unreasonable risk when self-assessed by the notifier against guidelines published by NICNAS

Once the notification has been made, the industrial chemical can be introduced.

Post-market monitoring would be undertaken in two ways:

- the introducer would be required to submit an annual compliance declaration to NICNAS to confirm that it is continuing to meet all of the requirements in relation to these chemicals, and that it is continuing to introduce in accordance with the original pre-introduction notification (i.e. no greater volume than that notified, same use etc); and
- NICNAS would ‘audit’ a proportion of the pre-market notifications annually. The purpose of the audit would be to ensure that introducers are acting in accordance with the notification. If NICNAS identifies non-compliance (such that the chemical does not meet the criteria for self-assessment and notification) the introducer would have the opportunity to either:
 - adjust their practice, such that the introduction meets the criteria for self assessment and notification, and re-notify NICNAS; or
 - submit an application for a certificate in respect of the introduction of the chemical.

Class 4 - Chemicals subject to notification and NICNAS assessment

<i>Indicative risk:</i>	Medium or high or significant uncertainty including the inability to self-assess as Class 3. Specifically including: <ul style="list-style-type: none">• high volume and/or high concentration chemicals that may lead to widespread exposure which increases the scale and distribution of risk• carcinogenic, mutagenic and reprotoxic (CMR) chemicals• persistent, bioaccumulative and toxic (PBT) chemicals• chemicals in relation to which there is significant uncertainty, such as nanomaterials.
<i>Eligibility:</i>	All new industrial chemicals that are not captured in the other classes would fall within this class.
<i>Pre-market process:</i>	Applicants would apply to NICNAS for a certificate.
<i>Assessment process:</i>	Refer detailed description of the assessment process below.
<i>Regulatory outcome:</i>	Issue of a certificate (with or without particulars of use and limitations on introduction) or refusal to issue a certificate.
<i>Post-market process:</i>	NICNAS audit compliance with: any limitations on introduction that have been imposed in connection with a certificate.
<i>Safeguards:</i>	The post-market reporting and auditing by NICNAS, information exchange with risk management agencies, information gathering powers and enforcement offences provide safeguards. State and Territory regulation of the use of these chemicals would continue to operate (as described for Class 2).

Further detail:

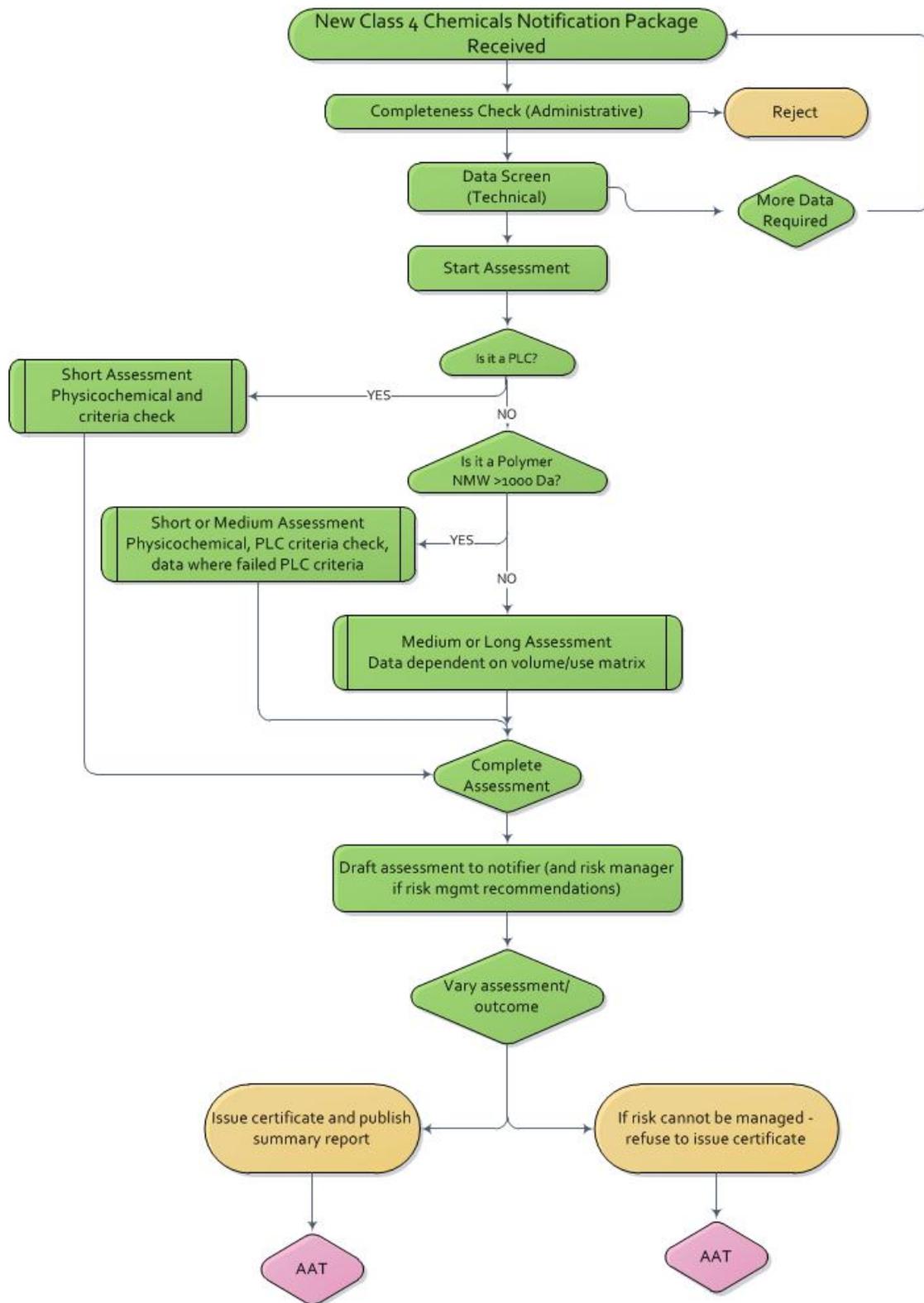
For further detail regarding the assessment process and the regulatory outcome for Class 4 chemicals, please refer to the following part.

B3. NICNAS new chemical assessments – Class 4

This Part describes the proposed assessment process for those chemicals that would require assessment by NICNAS prior to introduction. These would include:

- high volume and/or high concentration chemicals that may lead to widespread exposure which increases the scale and distribution of risk
- carcinogenic, mutagenic and reprotoxic (CMR) chemicals
- persistent, bioaccumulative and toxic (PBT) chemicals
- chemicals in relation to which there is significant uncertainty, such as nanomaterials.

There are several pathways to an assessment certificate within this class. For example, polymers of low concern (PLC) are proposed to be subject to an abbreviated assessment, while other polymers and chemicals would be subject to a more detailed assessment. The following diagram summarises the proposed assessment process for Class 4 chemicals.



Data requirements

The data requirements for Class 4 chemicals would be set out in Guidelines. NICNAS would take into account international data relating to hazard and would also take into account evaluations of that hazard data by comparable agencies.²⁵ Recognised comparable agencies would be identified in Regulations.

If international use and exposure data is available, NICNAS would consider this data but would need to be satisfied of its applicability and reliability in the Australian context.

Assessment process

It is proposed that the assessment of Class 4 chemicals would involve:

- an automated completeness check, subject to new IT systems;
- screening to determine whether there is sufficient information to conduct a risk assessment (and if not, a request for more information);
- the undertaking of a risk assessment;
- provision of a draft assessment to the notifier. The draft assessment would also be provided to relevant risk management agencies if NICNAS proposes to make recommendations relating to matters within the remit of other risk management agencies;
- revision of the assessment by NICNAS, based on any input from the notifier and/or risk management agencies;
- finalisation of the assessment and issue of both a report and the assessment certificate to the notifier (if granted). If recommendations are provided to risk management agencies, the final assessment would also be provided to the relevant risk manager(s); and
- publication of a summary report.

Different timeframes and fees would be prescribed for different types of risk assessment based on, for example, the nature of the chemical, the data and the level of uncertainty.

Each of these elements of the assessment process is discussed in more detail below.

²⁵ International data would only be able to be used where there is permission from the data owner.

Completeness check

It is proposed that this would be an automated check, based on an online submission, to ensure that the application includes the requisite fields of information.

If the application does not include the requisite fields of information, the application would not be accepted and the notifier would be advised.

The 'clock' would not start until the application is deemed to contain the required information.

Screening - sufficiency of information to conduct a risk assessment

It is proposed that applications would be screened to determine whether sufficient information is present to conduct a risk assessment.

If applications are screened, NICNAS would screen the data submitted within a statutory period to determine if there is sufficient information to conduct a risk assessment.

If there is not sufficient information, NICNAS would advise the notifier. The notifier would have a period of time within which to provide the necessary data. If the information was not submitted within the required/agreed timeframe, the application would be considered withdrawn.

The clock would be stopped during any time that NICNAS is awaiting information from the notifier. There would be a statutory timeframe set for this screening assessment.

Risk assessment

The nature of the risk assessment undertaken by NICNAS would depend on the chemical and the proposed use and volume.

For example:

- PLCs in this class would only require a physicochemical review and check against internationally harmonised hazard-based criteria;
- chemicals with low or medium hazard but with controlled use (e.g. manufacturing additive) would require less data than higher risk chemicals with wide use;
- hazardous chemicals with the potential to cause long-lasting, irreversible effects (e.g. mutagens, carcinogens, etc) with the potential for some public exposure would require more detailed risk assessment; and
- chemicals with potential for systemic human exposure or large-scale environmental exposure would also require more detailed risk assessment.

Following completion of the risk assessment NICNAS would provide a draft assessment to the notifier for comment.

If NICNAS is proposing to make recommendations to risk management agencies or to refuse to issue a certificate because it considers that the risks cannot be managed, a copy of the draft assessment would be provided to the relevant risk management agencies for comment including confidential commercial information.

The Director of NICNAS would consult with the proposed risk management advisory committee in relation to the adequacy of risk mitigation measures.

After receiving any comments, NICNAS would finalise the assessment of the Class 4 chemical and provide a report to the notifier. If risk management conditions had been recommended, the final assessment would also be provided to the relevant risk manager.

Publication of a summary report

It is proposed that NICNAS would publish a summary of the assessment of the Class 4 chemical on its website. The summary would include:

- the name by which the chemical is known;
- the use of the chemical (this may be expressed generally);
- any limitations of introduction on the chemical; and
- any recommendations made to risk management agencies.

Regulatory outcome

The outcome of an assessment of a Class 4 chemical would be:

- the issue of a certificate with or without particulars of use and/or limitations on introduction (these would replace permits); or
- refusal to issue a certificate if NICNAS cannot be satisfied, following consultation with risk management agencies, that the chemical can be used safely even with limitations on introduction and imposition of conditions.

Issue of certificate without limitations on introduction for a Class 4 chemical

In most cases, NICNAS would issue certificates that contain the particulars of use, but with no other limitations on the introduction. NICNAS may also choose to make recommendations to risk management agencies, if NICNAS considers that this is warranted. These recommendations would not be a condition of the certificate.

If NICNAS makes recommendations to risk management agencies:

- NICNAS may delay issuing a certificate until the imposition of any recommended risk management conditions by other risk management agencies.
- NICNAS would publish the recommendations as part of the summary of the assessment outcome. NICNAS would also publish the regulatory response of the risk manager (if any) after 6 months.

Issue of certificate with limits on introduction for a Class 4 chemical

If, despite any conditions able to be imposed by existing risk management agencies, the risks (or the uncertainty) cannot be managed without limits on the introduction of the chemical, then NICNAS would issue a certificate that is subject to limitations on one or more of the following:

- annual volume;
- concentration;
- sites of use;
- time period of the certificate.

This mirrors the existing power that NICNAS has in relation to permits (noting that Class 4 would capture some of the chemicals that were previously subject to permits).

All certificates would also be subject to conditions similar to the existing secondary notification conditions. Specifically, introducers would be required to notify NICNAS on becoming aware of changes (since the assessment) such as:

- any information that would reasonably be expected to reveal a greater degree of risk than previously assessed, including changes to the function or use of the chemical or increases to the amount of the chemical being introduced;
- in the case of a chemical not manufactured in Australia at the time of the assessment, the commencement of manufacturing in Australia;
- changes to the method of manufacture that may result in an increased risk of an adverse effect of the chemical on work place health and safety, public health or the environment; and
- additional information as to an adverse effect of the chemical on work place health and safety, public health or the environment.

Refusal to issue a certificate for a Class 4 chemical

If NICNAS cannot be satisfied that the chemical can be used safely even with limitations on introduction and imposition of conditions by risk management agencies, NICNAS may refuse to issue a certificate. The Director of NICNAS would consult with the proposed risk management advisory committee in relation to the adequacy of risk mitigation measures.

Refusal to issue a certificate would be expected to be the outcome in only the most exceptional cases.

Rights to reconsideration and review

If a notifier is dissatisfied with a decision of NICNAS relating to the issue of a certificate or the refusal of a certificate, the notifier may seek internal reconsideration by NICNAS and may also seek review by the Administrative Appeals Tribunal.

Entry on AICS

As is currently the case, if a chemical has been subject to a certificate that is not subject to limitations on use (other than particulars of use) or subject only to limitations as to volume or concentration, that chemical would automatically be entered on AICS after 5 years. A shorter time may be requested by the notifier.

It is proposed that AICS be maintained as a register of chemicals that would be able to be introduced by any registered introducer, subject to any limitation on use and notification conditions that may be entered on AICS.

B4. NICNAS post-market assessments – Existing chemicals and reassessments of previously assessed chemicals

It is proposed that there be three types of assessments that may be undertaken by NICNAS in relation to existing chemicals and reassessments of new chemicals:

- assessment of an application from a certificate holder for a variation of the certificate;
- assessment of an application from an introducer for a variation to the particulars of use on AICS; and
- a NICNAS initiated assessment of a chemical.

Application for variation of a certificate

It is proposed that a certificate holder could at any time request NICNAS to vary the certificate. For example, if the certificate was subject to limitations on introduction, the certificate holder may seek changes to these limitations. If the certificate was subject to certain particulars of use, the introducer may also seek to change the particulars of use.

The assessment process and timeframes would depend on the changes requested.

The decision would be notified to the notifier and the certificate amended if this were the outcome of the assessment of the request for variation. A NICNAS decision in

relation to a request for variation of a certificate would also be subject to internal reconsideration and review by the AAT.

Application to vary the particulars or limitations of use on AICS

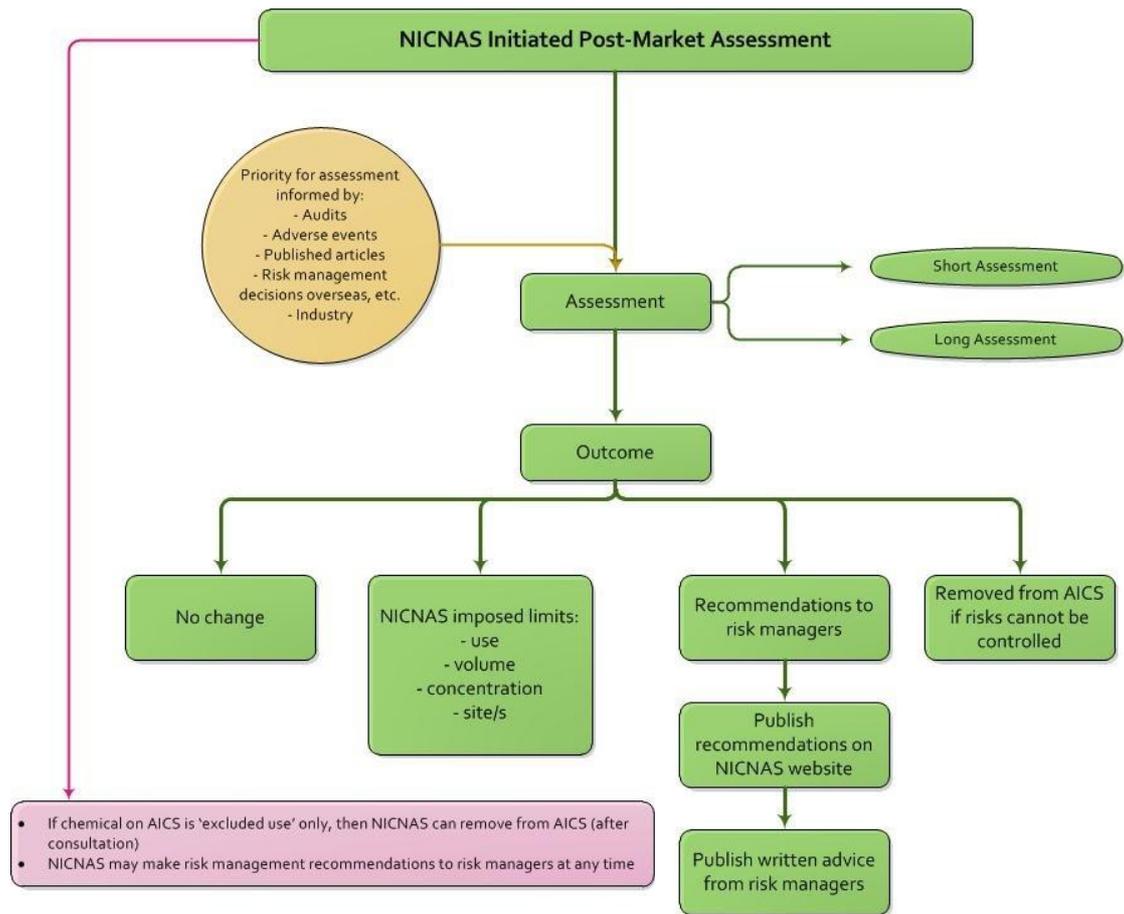
It is proposed that a registered introducer could at any time apply to NICNAS to vary the particulars of use that are on AICS. The assessment process would depend on the changes requested and whether a full risk assessment was required (e.g. a significant change in use).

NICNAS initiated assessment

The existing complex processes surrounding NICNAS initiated assessments (including for Priority-Existing Chemicals (PECs)) would be replaced with a more streamlined process which would be flexible enough to apply in any circumstance where NICNAS needs to initiate a post-market assessment of an industrial chemical

The proposed process would operate in a complementary way to the previously announced four year trial of the Inventory Multi-tiered Assessment and Prioritisation Framework (IMAP).

The proposed process for NICNAS initiated assessment is reflected in the following diagram and described in more detail below.



It is proposed that:

- NICNAS would prioritise chemicals for assessment based on risk and taking into account information received through:
 - information provided by introducers of the chemical (noting that conditions relating to secondary notification of chemicals would be maintained). NICNAS would also be able to call for information from introducers in order to inform its identification and prioritisation of chemicals for assessment
 - the results of any audits;
 - any adverse events;
 - any published articles;
 - any advice from local risk management agencies;
 - any risk management decisions from overseas; and
 - any advice from the public.
- the assessment process for NICNAS initiated assessments would involve:
 - determination of a proposed scope of assessment based on the chemical or class of chemicals under consideration;
 - publication of a notice advising of the commencement of an assessment of a chemical. The notice would describe the proposed scope of the assessment; and
 - if required, a mandatory call for information. This may not be necessary in all cases.
- following a call for information, NICNAS may decide not to proceed with an assessment or may decide to undertake a risk assessment. NICNAS would publish a notice advising the decision not to proceed with the assessment
- if a risk assessment is undertaken:
 - NICNAS would prepare a draft assessment and consult on the draft assessment. In most cases the consultation would be public consultation. However, the legislation would provide for more limited consultation, or no consultation, in circumstances where there are exceptional circumstances, for example, where the assessment indicates that risk management recommendations are urgently required.

The regulatory outcome following assessment of an existing chemical may be:

- no change to the entry on AICS and no recommendations to risk management agencies;
- no change to the entry on AICS but recommendations made to risk management agencies;

- inclusion of particulars of use or limitations of use (volume or concentration) on AICS; or
- removal of the chemical from AICS.

If NICNAS issues recommendations to risk management agencies, NICNAS would:

- publish these recommendations on its website; and
- include on the website the written advice provided by the relevant risk manager in response to the recommendation, after 6 months.

B5. Post-market monitoring and enforcement

The objective of reform in relation to post-market monitoring and enforcement is to ensure that NICNAS has the necessary tools to properly perform its monitoring and enforcement responsibilities.

It is proposed to align NICNAS' monitoring and enforcement provisions with those of comparable regulators.

It is therefore proposed that the ICNA Act be amended to:

- align any offence provisions with comparable regulators;
- enable NICNAS to issue improvement notices;
- enable NICNAS to issue prohibition notices; and
- enable NICNAS to require introducers (i.e. regulated entities) to produce information.

Improvement notices

An *improvement notice* would require a person to remedy a contravention or likely contravention, or the matters or activities occasioning the contravention or likely contravention, within a period specified in a notice.

For example, improvement notices would generally:

- state that the inspector is of the opinion that a contravention or likely contravention has occurred, or that there are certain matters or activities occasioning a contravention or likely contravention;
- state the reasons for that opinion;

- require that the person rectify the problem (the notice may also state the method by which the contravention is to be remedied);
- describe the date by which the problem must be rectified; and
- describe the person's review rights and describe the consequences of non-compliance with the improvement notice. For example, the legislation could provide that it is a criminal offence to not comply with an improvement notice.

The improvement notice would be underpinned with consequences for non-compliance, such as a criminal penalty and capacity for NICNAS to seek an injunction to restrain the person from engaging in the conduct that is prohibited.

Prohibition notices

A ***prohibition notice*** would prohibit a certain activity and requires an immediate action. A prohibition notice may mean an immediate stop is put to: an activity; the use of equipment or plant; or the use of a substance.

A prohibition notice would generally:

- state the basis for the prohibition, and specify the activity which the officer believes involves, or would involve, the risk, and the matters which give, or would give, rise to the risk
- if the officer believes that the activity involves a contravention or likely contravention, of a law, specify that provision and the basis for that belief
- include information about review rights and describe the consequences of non-compliance with the notice.

The prohibition notice would be underpinned with consequences for non-compliance such as a criminal penalty and capacity for NICNAS to seek an injunction to restrain the person from engaging in the conduct that is prohibited.

Power to obtain information and documents

There is currently no general power under the Act to enable the Director of NICNAS to call upon a person to provide documents or answer questions where the Director has reasonable grounds to believe there is non-compliance with the Act. NICNAS can require the production of documents and the answering of questions as part of an inspection, but not more generally. There is also only a limited power to request documents linked to Convention responsibilities (section 100G).

The specific power could be broadened to include a general 'notice to produce or attend' provision. This would enable NICNAS to require a person to provide information with respect to possible non-compliance.

B6. Other reforms

Registration of introducers

It is proposed that the system of registration of introducers remain largely unchanged.

Reporting of risk management agencies responses to NICNAS recommendations

It is proposed that NICNAS will publish risk manager responses to NICNAS recommendations at a defined time following the issuing of a certificate.

Treatment of confidential commercial information and the release of information

New industrial chemicals

Information relating to Classes 2, 3 and 4 would be exchanged between NICNAS and the risk management agencies on request. NICNAS and risk management agencies would be required to treat this information confidentially.

In relation to chemicals that would be in Classes 1 and 2, there is no notification to NICNAS and as such there would be no issues of release (or exemption from release) of confidential commercial information.

In relation to chemicals in Class 3 (that would be notified to, but not assessed by, NICNAS) there is no intention to publish identifying information in relation to these chemicals. As such there would be no issues of release (or exemption from release) of confidential commercial information.

In relation to NICNAS assessment of Class 4 chemicals, it is proposed that:

- in most cases, the draft assessment would not be provided to anyone except the notifier (to check accuracy). However, if during the assessment NICNAS considers that it may make recommendations to risk management agencies, NICNAS would provide a copy of the draft assessment to the relevant risk management agencies. The assessment would be provided in its entirety with no removal of any confidential commercial information. The Act would contain an offence for the mishandling of confidential information.
- following assessment NICNAS would:
 - provide a copy of the final assessment to the notifier
 - if recommendations were made to risk management agencies, provide a copy of the final assessment to the relevant risk management agencies

- publish on the NICNAS website a summary of the outcomes of the assessment. This summary would include:
 - the name by which the chemical is known
 - the use of the chemical (this may be expressed generally)
 - any limitations of introduction on the chemical
 - any recommendations made to risk management agencies
- A stand-alone assessment report would no longer be prepared.

Existing industrial chemicals

If NICNAS initiates an assessment of an existing chemical, NICNAS may call for information from introducers or others.

If such information is provided to NICNAS, the person providing the information may request that it be treated as confidential commercial information and not be released. If NICNAS approves such a request, this information would not be released publicly. However, this information may be released to risk management agencies if it is directly relevant to them.

Use of foreign schemes/international assessments

It is proposed that:

- NICNAS would continue to take into account international data relating to hazards of industrial chemicals and also assessments from comparable agencies.
- any international use and exposure data would need to be further considered by NICNAS to determine whether it is appropriate and reliable in the Australian context.
- NICNAS would not automatically issue or reject a certificate for a new industrial chemical (nor would it automatically amend AICS) because of the action of another regulatory authority.

The four new classes of chemicals provide closer alignment with overseas classes/categories such that international data and assessment are more likely to be available.

NICNAS would continue the current approved foreign scheme arrangements for the recognition of comparable agencies. In addition, NICNAS would continue its current international harmonisation work to seek uniformity in approach with Australia's trading partners and advance bilateral arrangements to facilitate consideration of overseas reports and assessments.

Chemicals in articles and mixtures

It is proposed that the Act be amended to further clarify that an article or a mixture is an excluded industrial chemical not subject to NICNAS regulation. Individual chemicals within mixtures would continue to be regulated by NICNAS. Where chemicals are proposed for use in a mixture, NICNAS would consider the industrial chemical in this context (including the influence of, and interaction between, the mixture and the chemical) where the methodology for doing so was available. Individual chemicals that are released or leach from articles would continue to be regulated by NICNAS. This reflects the current situation but it would be useful to be more explicit in the legislation.

Chemicals in cosmetics

It is proposed that the ACCC take responsibility for administration of the *Cosmetics Standard 2007* (the Cosmetics Standard).

This would mean that the ICNA Act would be amended to remove all references to the Cosmetics Standard and the administration of those standards by NICNAS.

NICNAS would continue to regulate the introduction of industrial chemicals (ingredients) for use in cosmetics (but would not regulate final products), according to the chemical classes.

In order to better align with the European model for cosmetics regulation, an option is to amend the Cosmetics Standard to include 'permitted lists'. This would require further consideration by the ACCC following transfer of the Standard. Controlled lists could be picked up through existing mechanisms such as the Standard for the Uniform Scheduling of Medicines and Poisons.

Responsibilities under Stockholm and Rotterdam conventions

It is proposed that regulations relating to the import and export of chemicals in accordance with the Rotterdam Convention be removed from the ICNA Regulations. This would become the responsibility of DSEWPaC.

The ICNA Act would continue to include Part 5A, which includes obligations on the Director of NICNAS to provide information to the national authority in relation to certain Rotterdam Convention matters.

Under the Stockholm Convention, NICNAS has no import or export related responsibilities. Rather, NICNAS takes into account Persistent Organic Pollutant (POPs) criteria specified in the Stockholm Convention when undertaking assessments of new and existing chemicals. It is proposed that NICNAS would continue to do this under the new framework.

Governance

It is proposed that a non-legislative committee be established consisting of NICNAS and the national risk management bodies dealing with work health and safety, public health, environment, transport and consumer safety. The committee would consider issues relating to risk management recommendations and NICNAS' relationship with risk management agencies. Issues and view from relevant state and territory risk management agencies will be collated through the national risk management bodies.

The Director of NICNAS would remain able to convene advisory committees, and participate in cross-jurisdictional committees established by other agencies, on issues related to the notification and assessment of industrial chemicals, and interactions between risk assessment and risk management activities.

Attachment C - Estimate of chemicals likely to fall within each class (Option 3)

The 351 new chemical assessments completed by NICNAS during a two-year period (September 2010 - September 2012) were analysed and grouped according to the four proposed new classes of chemicals.

The purpose was to estimate how many new chemicals are likely to be allowed entry without an assessment, or assessed pre-entry by NICNAS under the proposed framework, and the type of certificate that may be issued.

Chemicals considered to be Very Low or Low Risk

In addition to the chemicals exempt from notification during the period September 2010 – September 2012, 110 chemicals were assessed by NICNAS that would under the proposed classes be eligible for automatic entry or pre-entry notification (self-assessment against criteria).

It is possible that the total number of chemicals introduced under pre-entry notification (self-assessment against criteria) could increase as companies may have decided not to introduce new chemicals at volumes between 100 and 1000kg/year due to current notification and assessment requirements. The proposed New Chemicals Framework encourages the introduction of chemicals meeting these very low or low risk criteria over chemicals that are likely to pose a higher risk which would require assessment in Class 4.

Eligibility ²⁶	Number of chemicals
<1,000 kg non-cosmetic (no unreasonable risk)	106
<1% non-cosmetic (no unreasonable risk)	4
R&D site-limited manufacture (non-nanomaterials)	0
R&D nanomaterials <10 kg	0
Transshipment	0 ²⁷

Potentially Medium/High Risk chemicals

Pre-entry assessment by NICNAS is proposed for Class 4 chemicals.

²⁶ Chemicals in this Very low or Low Risk category were formerly introduced under permits (mainly low volume chemical (LVC) permits) or certificates.

²⁷ If you are accessing this document using a screen reader and having difficulty reading the table data, please contact our the NICNAS Review Team on email NICNAS.review@health.gov.au.

In the two-year period, there were 241 chemicals assessed under a permit or certificate category that met eligibility as a Class 4 (medium/high risk) chemical.

According to the proposed new schema, if the outcome of an assessment is that the chemical introduction is permitted, a certificate is issued with or without limits on introduction (including time limits, location, volume and concentration).

Using this approach, the 241 chemicals previously assessed by NICNAS were divided into one of three regulatory outcomes: no limits on introduction; limits on introduction and no certificate issued.

Certificate Types ²⁸	Number of chemicals
No limits on introduction ²⁹	
- without risk management recommendations	120
- with risk management recommendation	60
Limits on introduction ³⁰	61
No certificate issued	0 ³¹

²⁸ Chemicals in this Medium/High Risk category were formerly introduced under permits, or certificates with import/manufacture quantity >1,000 kg/year.

²⁹ Includes all PLCs, plus polymers or chemicals that were not considered to be of concern to human health and environment for the assessed use. Any proposed uses outside the 'particulars of use' of the assessment would require a request for variation of a certificate/AICS.

³⁰ Includes polymers or chemicals where risk was considered acceptable only within the strict confines of the assessed use, but the risk is high if used outside of the assessment parameters and a secondary notification condition (s64(1)) was included in the assessment. An example of a secondary notification condition was that a chemical was not to be released into freshwater systems. Some may have limits on introduction and a time limit. In some cases it was uncertain whether the risk of the chemical would require a limit on introduction or whether the risks could be managed within the 'particulars of use'.

³¹ If you are accessing this document using a screen reader and having difficulty reading the table data, please contact our the NICNAS Review Team on email NICNAS.review@health.gov.au.