REGULATION IMPACT STATEMENT

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

November 2014

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Preface

The primary objective of reform of the ICNA Act is to focus regulatory effort on higher risk chemicals. The role of NICNAS, which is to assess the human health and environmental risks of chemicals, will not change as part of this reform. The proposals in this paper are consistent with the Australian Government's *Industry Innovation and Competitiveness* and *Deregulation Agendas*. Achieving efficiencies in regulatory processes by cutting red tape and improving competitiveness and innovation in the industrial chemicals market will be balanced with the need to adequately safeguard human health and the environment. It is important to note that changes to the institutional and regulatory arrangements for chemicals more broadly are outside the scope of this RIS.

This RIS sets out four options, including a base case, as possible arrangements for achieving the primary objective of this reform. Each of the options, except for the base case, shares the following similarities:

- introducing a three-tiered classification system for industrial chemicals, according to risk;
- expanding the criteria for self-assessment of chemicals by the introducer;
- focusing NICNAS's resources on assessing the human health and environmental risks for higher risk chemicals;
- modernising NICNAS's monitoring and compliance powers to better suit pre-market self-assessment and notification, premarket risk assessment, risk management and post-market assessments;
- better utilisation of international assessment information; and
- retaining NICNAS's primary function as a risk assessor that provides recommendations to risk management agencies.

The options differ by the:

- methodology applied for classifying the risk of a chemical based on different volume, category of use, hazard and exposure metrics; and
- level of pre-market scrutiny applied to chemicals in each class, under each option, including the requirements for pre- and post-market assessments.

Each option, compared to the base case, is expected to deliver efficiencies for industry by reducing the number of 'new' chemicals requiring pre-market assessment by NICNAS to less than 2% in all cases.

In response to stakeholder feedback, this iteration of the draft RIS has been revised to provide:

- greater clarity of the risk classification of chemicals for all options, except the base case;
- detail of intended risk classification criteria for each option;
- additional detail on the impact of reforms, including cost;
- revised implementation timeframes;
- an overview of international industrial chemicals regulatory arrangements, and utilisation of international assessment information for each option; and
- clarification of proposed changes to cosmetics and cosmetic ingredient regulation.

Executive Summary

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a statutory scheme within the Health portfolio that assesses the health and environmental risks associated with the importation, manufacture and use of industrial chemicals. NICNAS provides information and makes recommendations to Commonwealth, state and territory bodies with responsibilities for the regulatory management of industrial chemicals to aid in the protection of the Australian people and the environment.

Generally, under the Scheme, industrial chemicals are introduced as either 'existing' chemicals or 'new' chemicals, as follows:

- Approximately 40,000 chemicals are listed on the Australian Inventory of Chemical Substances (AICS). Chemicals listed on AICS do not require further pre-market assessment and may enter the Australian market without notification to NICNAS. These are categorised as 'existing chemicals'.
- Approximately 9,000 chemicals each year are introduced into Australia under current exemption provisions of the ICNA Act. These chemicals may enter the Australian market without pre-market assessment, but require annual (post-market) notification to NICNAS. These are categorised as 'new chemicals'.
- Approximately 300 new chemicals each year do not fall under the exemption provisions of the ICNA Act and must be assessed by NICNAS before being introduced into Australia (pre-market). These 'new' chemicals must not enter the Australian market until NICNAS has completed an assessment and issued an assessment certificate or permit.

There have been strong calls from both industry and community sectors for improvements to the Scheme. Industry seeks more timely access to market for newer, potentially safer chemicals (not meeting exemption criteria) and believes the existing arrangements encourage the continued use of older, un-assessed or potentially more harmful chemicals (listed on AICS). Industry has expressed frustration regarding regulatory costs and delays associated with pre-market assessments, leading to lost market opportunities and reducing its ability to innovate and compete in the market. Community groups, on the other hand, want assurance that risks to the Australian people and the environment from both new and existing industrial chemicals will continue to be appropriately assessed and mitigated.

Throughout 2012-13, an extensive review of the Scheme was conducted in consultation with stakeholders from industry, all governments and the public. The review investigated how the existing regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes.

The review identified a number of problems affecting the delivery of efficient and effective regulatory outcomes:

1. *NICNAS's assessment framework is not sufficiently based on the likely risk of a chemical*

   The current rule-based assessment framework does not adequately take into consideration the potential risk of a chemical when determining the level of assessment required, either for the introduction of new industrial chemicals or when assessing those already on the market.

2. *Legislative requirements create inefficient regulatory processes*

   The *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act) is very prescriptive in the requirements for notification and assessment of new and existing industrial chemicals. This has resulted in a notification framework that is overly complex and restricted by cumbersome administrative processes.

3. *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; in some circumstances this creates a misunderstanding about regulatory coverage.

The Productivity Commission in its 2008 *Chemicals & Plastics Regulation: Research Report* notes that there are several grounds for government policy intervention in this industry. Specifically, there are significant externalities and information asymmetries concerning the risks associated with the hazardous (toxic, flammable, corrosive or explosive) nature of some of the chemicals or products which contain them. There is also a public good argument that protection of public health, the environment and national security is underprovided by the private sector[1].

The review identifies four regulatory reform options, including the status quo. As the case for Government intervention in the use of industrial chemicals to safeguard public health and the environment

[1] Productivity Commission Research Report: Chemicals & Plastics Regulation, July 2008. Online reference: http://www.pc.gov.au/__data/assets/pdf_file/0017/82331/chemicals-plastics-regulation.pdf

is well established and supported by all key stakeholders, non-regulatory options are not considered.

Option 1: *Base case – make no changes to the current scope or activities of NICNAS.*

Option 2: *Focus on post-market regulatory controls for both new and existing industrial chemicals with the assessments requirements informed by category of use and volume.* By reducing pre-market barriers to the introduction of new chemicals, the onus would be on industry to manage the risks of introducing new chemicals, which would allow a wider range of new chemicals to be introduced immediately following notification to NICNAS without the delays associated with assessment. However, this would be safeguarded by strengthening NICNAS's post market powers. NICNAS would continue to make risk management recommendations arising from post-market assessments, but the capacity for NICNAS to apply any pre-market controls would be removed.

Option 3: *Pre- and post-market regulatory controls for new chemicals, post-market regulatory controls for existing chemicals, with the assessment requirements informed by hazard and exposure.* This would be achieved by focusing pre-market assessment resources on new chemicals with an anticipated higher risk (retaining NICNAS's capacity to undertake a thorough risk assessment for potentially high risk chemicals), while allowing 'lighter touch' treatment of new chemicals of lower regulatory concern. NICNAS would also have the ability to initiate assessments of existing chemicals based on identified concerns. NICNAS would continue to be able to make recommendations to risk management agencies, and/or impose controls in the absence of existing risk management agencies where necessary to ensure regulatory coverage.

Option 4: *Continued focus on pre-market regulatory controls for new chemicals and post-market regulatory controls of existing chemicals, with the assessment requirements informed by category of use and volume*.

Each of Options 2-4 proposes a different balance between the pre-market and post-market controls, with associated impacts on both the efficiency and effectiveness of regulatory outcomes. For Option 2, NICNAS pre-market assessments would impact ~1.0% of the approximately 9,000 new chemicals introduced each year. For Option

3 this estimate drops to ~0.75% and for Option 4 increases to approximately 2.0%.

Parties potentially impacted by any regulatory change include the community, industry, NICNAS itself and risk management agencies. These stakeholders hold diverse views and this is reflected by costs and benefits not being uniformly distributed between them across the options.

Taking into account the views of stakeholders and the analysis of impacts, Option 3 has been identified as the preferred option. Option 3 represents a significant reduction in regulatory burden and strikes a balance between pre- and post-market controls that should minimise barriers to entry for new lower risk chemicals while continuing to appropriately manage higher risk chemicals, including a greater focus on existing chemicals.

Option 3 is expected to result in a reduction in the costs to industry associated with new chemical assessments, with the additional benefit of faster entry to market of new, safer chemicals with lower anticipated risk to public health and the environment. Industry will also benefit from the greater alignment with international regulatory arrangements, reducing jurisdictional variation in data requirements.

The proposed “risk-based” reforms enhance the use of international assessment materials and would be expected to reduce (if not eliminate) delays to market for all but the highest risk chemicals. The reforms outlined in Option 3 would:

- allow for immediate introduction of new chemicals following self-assessment and notification for those chemicals that pose a low risk either due to their hazard profile or intended use. The availability of international assessment materials, for example a European REACH dossier, would be expected to meet the information needs of a self-assessment requirement (with consideration of exposure variables relating to its proposed use in Australia);
- streamline pre-market risk assessment of higher risk chemicals by utilising international hazard or exposure assessments;
- as an estimate, leave substantially less than 1% (approximately 100 substances) of all new chemical introductions per year requiring pre-market risk assessment by NICNAS, based on their higher or uncertain risk profiles.

The Australian community also benefits from earlier introduction of industrial chemicals, because products with a lower risk profile are allowed a more streamlined assessment, while public health and environment outcomes are delivered through continued assessment of high risk new chemicals and a greater focus on unassessed

existing chemicals, including a greater degree of flexibility in responding to new information.

The preferred option also provides NICNAS with appropriate regulatory capability to enforce controls commensurate with the risk of the chemical, including where significant risks are present, applying limitations that ensure national regulatory coverage.

The preferred option provides for an appropriate balance of safeguards for human health, worker safety and the environment whilst reducing regulatory burden and unnecessary red tape for introducers of new chemicals. This option is expected to achieve significant efficiencies and cut red tape for industry by reducing the number of NICNAS pre-market assessments from 300 (of the approximately 9,000 new chemicals introduced each year) to 100. This will improve competitiveness and increase innovation in the chemical sector and allow the Australian community to have timelier access to lower risk (safer) chemicals. The introduction of the risk-based classification system will ensure that safeguards are in place to protect human health, worker safety and the environment, whilst placing less administrative burden on industry. In addition to the safeguards proposed in this option, the Government will continue to implement the Inventory Multi-tiered Assessment and Prioritisation (IMAP) for existing chemicals.

This Regulation Impact Statement (RIS) will assist the Australian Government to make decisions regarding any reform recommendations proposed in relation to NICNAS.

Subject to Government consideration of the review's findings, amendments to the ICNA Act and the development of delegated legislation (Regulations and Guidelines) would proceed. Further consultation opportunities will be available both on the detail of legislative drafting instructions, and the publication of the draft legislation.

Part A: Context

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

In finalising options for reform, the review team took into account:

- the objectives of the Australian Government's *Industry Innovation and Competitiveness and Deregulation Agendas*;

- that the broader regulatory framework for chemicals falls within the mandate of the Standing Council on Chemicals[2], and is out of scope for the purpose of this reform;

- the objective of this review was "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";

- that the role of NICNAS, which is to assess the human health and environmental risks of chemicals, will not change as part of this reform;

- the Australian Government Guide to Regulation: Ten Principles for Australian Government Policy Makers; 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, during which21 written submissions were received;
  - an internal review of NICNAS's arrangements, functions and processes;
  - ongoing discussions with NICNAS and other Commonwealth agencies;
  - the publication of a paper entitled: *Discussion Paper: Review of the National Industrial Chemicals Notification and Assessment*

[2] On 10 October 2014, the Council of Australian Governments agreed that SCOC would recommend a reform pathway to the regulatory framework for chemicals to improve its efficiency by the end of 2014.

Scheme (NICNAS) - June 2012. This Discussion Paper identified a range of options for reforming NICNAS and sought public comment on these options: 46 submissions were received;

- 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;
- the release of the draft RIS to stakeholders for comment in 2013: 21 written submission were received;
- engagement with key industry associations and community stakeholders in Canberra on 6 and 20 August 2013, respectively; and
- additional engagement with key industry associations and consumer, community, environment and professional groups and associations on 24 and 25 July 2014 to provide comment on revised options for reforming NICNAS.

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 on reforms in Australia's industrial chemicals sector.

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 four 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: Focus regulation on post-market controls for both new and existing industrial chemicals;
  - Option 3: Graduated, risk-based approach to the regulation of industrial chemicals; and
  - Option 4: Pre-market emphasis on the regulation of new industrial chemicals, with continued post-market review of existing chemicals.

- describes the stakeholders (namely, the community, industry, NICNAS and other risk management agencies) and analyses the impacts of each of the options on each party (Part G);

- describes the public consultation that has informed the development of the options and the RIS (Part H);

- draws a conclusion and suggests a recommended option (Part I); and

- identifies a proposed approach to the implementation of the preferred option, along with opportunities for regular review (Part J).

Attachments to this document provide further detail of the costs associated with the existing processes (Attachment A) and

comparison of international approaches to chemicals' regulation (Attachment B) and fee structures (Attachment C).

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, plasticisers, 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 contributed in order of $11.7 billion to the Australian economy and provided approximately 74,822 jobs during 2011-2012[3].

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[4].

Chemicals regulation in Australia

The institutional and regulatory arrangements for chemicals in Australia 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 the regulation of the chemicals industry have been 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

[3] Source: Australian Bureau of Statistics, 8155.0 Australian Industry 2011-12. 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

[4] Chemicals & Plastics Regulation: Productivity Commission Research Report, July 2008. Online reference: (http://www.pc.gov.au/projects/study/chemicals-plastics/docs/finalreport).

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

Australian Government chemicals assessment and registration schemes

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

- therapeutic goods are regulated by the Therapeutic Goods Administration (TGA);
- the use of chemicals in food and food additives is subject to standards set by Food Standards Australia New Zealand (FSANZ) and enforced under state/territory food laws;
- pesticides and veterinary medicines are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA); and
- industrial chemicals[5] are notified to, and assessed by, NICNAS.

Role of NICNAS

Overview

NICNAS is a statutory scheme established by 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 the safe use of industrial chemicals.

Under the ICNA Act, a new industrial chemical cannot be introduced into Australia unless it has been notified to, or assessed by, NICNAS and either a permit or certificate has been issued, or it meets the requirements for introduction without assessment by NICNAS (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

[5] NICNAS is a scheme for assessing the risks of chemical substances, which means that it assesses the individual ingredients found within products, rather than formulated end use product.

relevant government risk management agency which then determines the controls to enact and enforce. Recommendations are also provided to the notifier or applicant.

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.

NICNAS' core functions are described below.

New chemicals - notification and assessment activities

Under the ICNA Act it is an offence to introduce (i.e. import or manufacture) a new industrial chemical into Australia, except in the following circumstances:

- 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 five different types of permits);
- the person holds an assessment certificate; or
- if the chemical is defined as an existing chemical[6].

[6] Under the ICNA Act, **existing chemicals** (i.e. those listed on AICS) may be introduced (within specified conditions of use, where applicable) without prior notification to NICNAS.

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. Exemptions currently cover:

  - research and development use where introduction is <100 kg per annum;
  - chemicals manufactured in Australia solely for the purpose of research, development or analytical work and site-limited (no volume restriction);
  - transhipment where the chemical is introduced at a port or airport and remains subject to the control of Customs and leaves Australia within 30 days (no volume restriction);
  - non-cosmetic chemicals where there is no unreasonable risk and proposed introduction is <100 kg per annum;
  - cosmetic chemicals at concentrations of <1% (must meet criteria e.g. not hazardous, not a dangerous good); and
  - cosmetic chemicals where there is no unreasonable risk and introduction is <100 kg per annum.

  For both cosmetic exemptions, the chemical is not eligible if it is a preservative, colouring agent, UV filter or prohibited or restricted in EU or USA.

  Overall, new chemicals currently eligible for exemptions from notification and assessment are low risk chemicals.

  In 2012-13, approximately 9,000 chemicals were reported to have been introduced through exemptions[7].

- ***permits*** are available for chemicals that meet other legislated criteria. Permits are issued for low to high hazard chemicals, but regulatory controls can be applied through permit conditions to reduce the risk e.g. maximum allowable quantity or concentration limits. 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-

[7] 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.

limited and may be renewed. Compliance with conditions of use is monitored and enforced by NICNAS. The ICNA Act currently identifies criteria for the following permit categories:

- chemicals introduced for commercial evaluation (maximum four tonnes in a maximum period of two years);
- chemicals for controlled use including export only (used in highly controlled circumstances where the chemical meets low hazard plus human and environmental exposure criteria)[8];
- introduction of chemicals at low volumes (up to 1,000 kg per annum). These chemicals must meet low hazardous criteria for 100 kg to 1,000 kg per annum, otherwise limited to maximum 100 kg per annum;
- Ministerial approval to introduce a chemical before the assessment is completed where the public interest determines that the chemical is introduced without delay and it does not pose a risk to human health and environment (section 30 permit);
- Early Introduction Permits that must be made in conjunction with a Standard, Limited or Polymer of Low Concern (PLC) notification (refer discussion below in relation to certificates). This is not a stand-alone permit category. The 'early introduction' refers to the permit allowing introduction of the chemical before the assessment is completed. The permit is in force only until the certificate is issued.

In 2012-13, 119 permits were issued by NICNAS[9].

- ***assessment certificates*** are required for all new chemicals that do not meet the exemption or permit criteria. These chemicals range from low to high risk chemicals. The data requirements vary depending on the category of introduction which is based on volume or type of chemical proposed to be introduced. There are four major certificate assessment categories:

  - PLC – polymers of low concern which meet specific criteria that would indicate that they pose a low risk to human health and/or the environment.
  - Limited– for chemicals introduced at less than 1,000kg per year and high molecular weight polymers that do not meet the PLC criteria.

[8] Export only does not have to meet hazard/exposure criteria but must demonstrate low risk.

[9] unpublished data provided by NICNAS

[6] Ibid

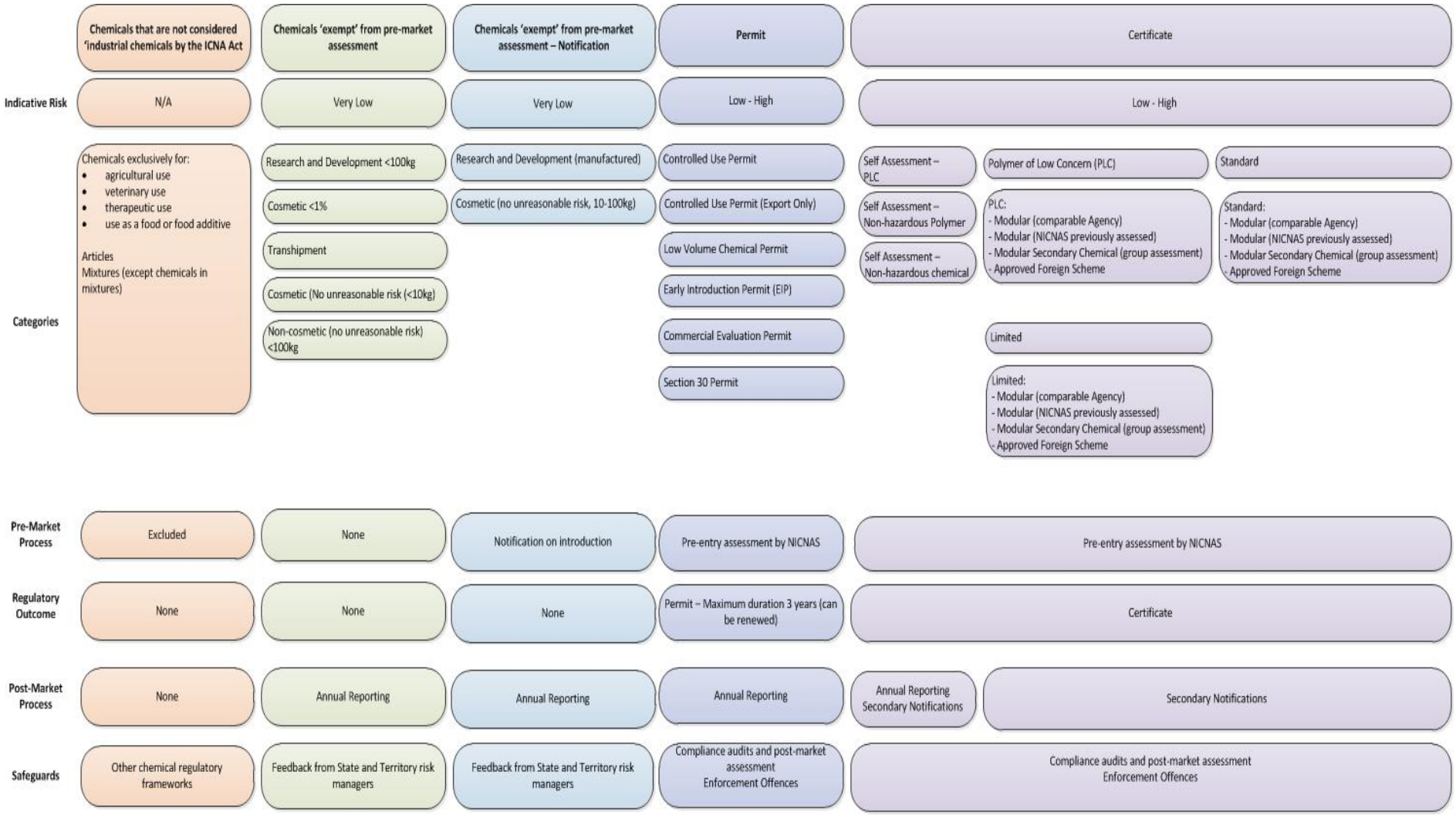
- Standard - for chemicals, biopolymers and low molecular weight polymers imported or manufactured at greater than 1,000 kg per year and which do not fulfil the requirements of any other certificate category.
- Self-assessment – for non-hazardous chemicals, polymers or PLC.

Following an assessment, NICNAS issues a detailed assessment report. This report includes hazard identification, risk assessment and recommendations for regulatory controls and conditions of use.

Once NICNAS issues an assessment certificate, the notifier 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 2012-13, NICNAS issued 162 assessment certificates for new chemicals. Of these, NICNAS recommended that risk management measures be implemented by risk management agencies for 40 chemicals[6].

The following diagram (Diagram 1a) details the current industrial chemicals framework.



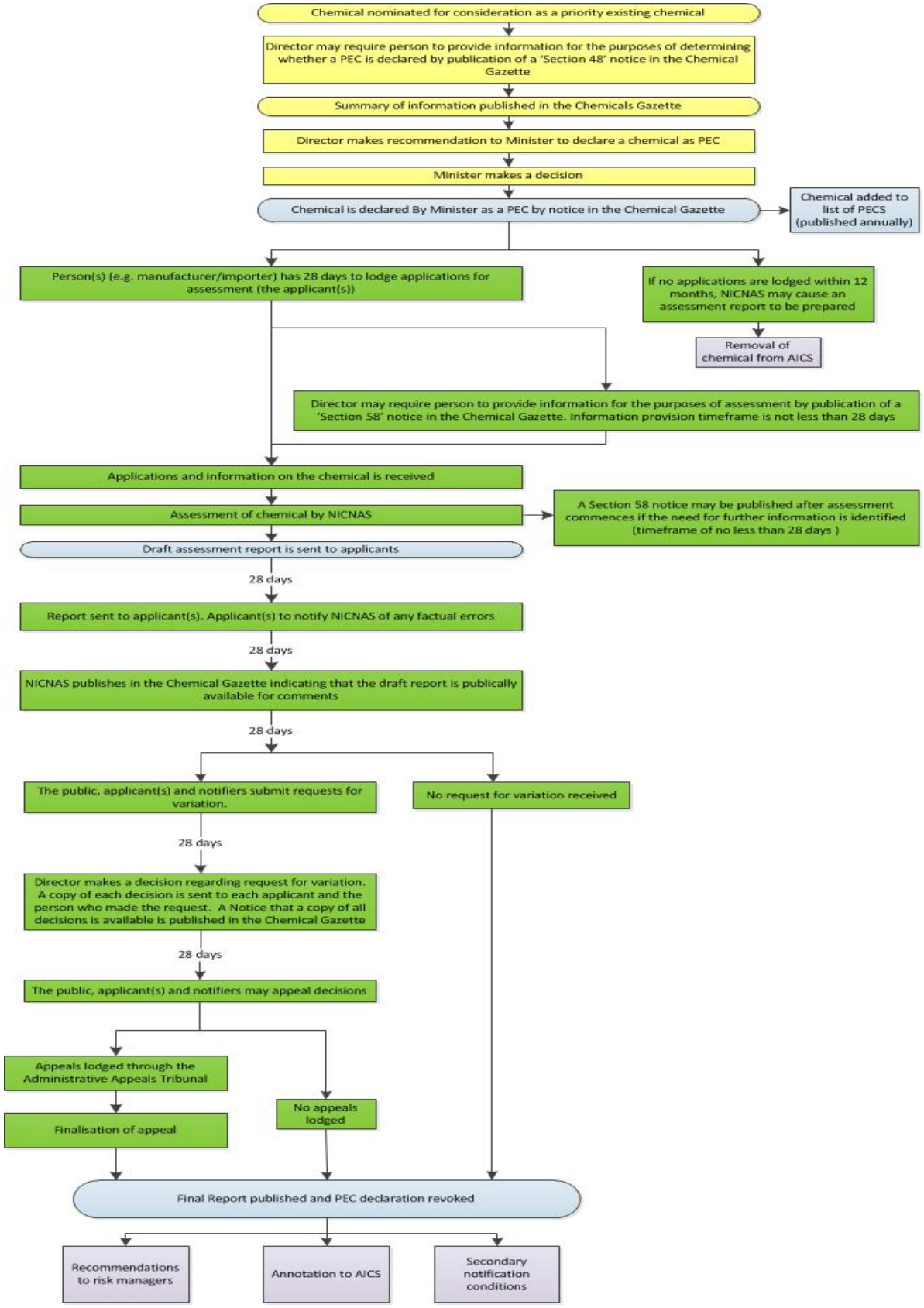
- ***AICS*** - For new chemicals that have been subject to an assessment certificate, the introducer may choose to apply to NICNAS to have the chemical listed on AICS. Once listed on AICS, anyone can import or manufacture the chemical. If the introducer does not apply to have the chemical listed on AICS, it is automatically listed on AICS after five years. 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)[10] can be declared a Priority Existing Chemical (PEC) which provides for a closer examination and a detailed risk 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. Diagram 1b details the current requirements for a PEC assessment.

  There are approximately 40,000 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.

[10] A naturally occurring chemical is deemed to be on AICS.

The following diagram (Diagram 1b) details the current requirements for a PEC assessment.



- ***secondary notification*** - During the validity of a certificate (usually five 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 2012-13 NICNAS assessed one secondary notification[11].

- ***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 2012-2013, there were 5,290 registered introducers of relevant industrial chemicals[12].

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.

[11] unpublished data provided by NICNAS

[12] Ibid.

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 2012-13, NICNAS, as part of its compliance programme, undertook 27 site visits, conducted 1,200 desk audits and had 34 active compliance cases[13]. 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 four new chemicals and 35 new chemicals being included in annual reporting.

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, state and territory agencies regulate and enforce work health and safety laws in their jurisdictions;

- environmental management: Commonwealth, state and territory agencies monitor and manage industrial chemicals in the environment[14];

- the land transport of dangerous goods, which is regulated under state and territory legislation, reflect the Australian Code for the Transport of Dangerous Goods by Road and Rail (the Code); and

[13] NICNAS, NICNAS Annual Report 2012-13, Canberra 2013. Online reference: (http://www.nicnas.gov.au/__data/assets/pdf_file/0017/8252/NICNAS_Annual_Report_2012-13.pdf)

[14] 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.

- 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 use[15].

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 recommendations[16].

Comparison of International Chemical Regulatory Schemes

Overview

Key features of the chemical regulatory schemes of Australia, New Zealand (NZ), the United States of America (USA), Canada and the European Union (EU) are summarised in Attachment B. Broadly speaking, the industrial chemicals legislation in the US, Australia and Canada places the burden of proof on regulatory agencies to demonstrate that chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals) do not pose a risk to human health or the environment. In contrast, the EU generally places the burden on chemical companies to ensure that chemicals do not pose such risks or that measures are identified for handling chemicals safely. The New Zealand legislation allows companies to self-assess whether a chemical is hazardous as well as to self-determine the applicability of Group Standards for control of hazardous chemicals.

The regulation of new chemicals and existing chemicals in each international jurisdiction is discussed below.

New Chemicals

Australia, New Zealand, the EU, Canada and the USA have developed categories for notifying new chemicals based on the principle that the chemicals posing the highest risk require the highest level of assessment.

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

[16] Existing Chemicals Review – National Public Engagement Strategy (http://www.nicnas.gov.au/__data/assets/pdf_file/0011/6050/ECR-Public-Engagement-Strategy-report.pdf.)

The new chemicals regulations across the jurisdictions stratify risk differently based on introduction volume, hazard, prior regulation or a combination thereof.

For example, each international jurisdiction has exemption categories for certain chemicals, which may be defined by an introduction volume threshold. These thresholds vary within each jurisdiction depending on the category of the chemical (including its intended use/purpose). An added complexity is that the categories of chemicals subject to exemptions may also vary between international jurisdictions, including the criteria defining each category. As a result, a chemical being introduced at a certain volume may be exempt from new chemicals regulation in one jurisdiction, but may require assessment in another jurisdiction.

Further, each jurisdiction has set different criteria and data requirements for their assessment categories, making alignment/harmonisation of international criteria and volume thresholds complex.

Existing Chemicals

Different international jurisdictions have different programmes to assess the 'grand-parented' [17]chemicals on their inventory. Canada has the Chemicals Management Plan under which it is assessing existing chemicals in commerce in Canada. The USA has the Toxic Substances Control Act (TSCA) Work Plan. The EU has redefined all existing chemicals as new chemicals under REACH. In all jurisdictions (except EU), the burden of proof for evaluating the risks of existing chemicals rests with the regulatory authorities rather than on chemical introducers.

Two key areas of difference across jurisdictions are: obligations on introducers to provide data; and the ability of regulators to restrict or prohibit the introduction of existing chemicals.

Fees

Australia, NZ, Canada, USA and the EU apply varying levels of fees and charges and penalties to the introducer of a chemical for registration, new chemicals assessment, and inventory searches and changes. The extent to which these fees and charges cover the full costs of the relevant scheme (ie 100% cost recovery) varies between the jurisdictions.

In Australia, NICNAS operates on a full cost recovery basis, with assessment of new chemicals charged on a fee for service basis and all

[17] 'Grand parented' chemicals are those chemicals added to an inventory at its establishment, without assessment, due to them being on the market at that time.

other activities funded by a levy (NICNAS registration) on those who import or manufacture industrial chemicals in Australia.

In Canada fees are intended to recover approximately 20% of the New Substances Program's total annual costs[18] and accordingly, the fees for a new chemicals assessment are lower than the NICNAS fees. Likewise, the existing chemicals programme and compliance activities are funded by the Canadian Government, whereas these activities are fully cost recovered from the regulated industry (in the form of a levy) in Australia.

The fee structure for chemicals regulation has many variables, making it difficult to achieve meaningful comparisons of fees between jurisdictions. Table 1a below provides a high level comparison of the fees for assessment of new chemical substances and whether full or partial cost recovery arrangements are in place. Further detail on the fee structure of industrial chemicals regulation schemes for USA, Canada and European Union is included at Attachment C.

Table 1a: International comparison of new chemical assessment fees and cost recovery arrangements

	Australia	New Zealand	USA	Canada	European Union
New Chemical Assessment Fee (approx.) (AUD)	$2,800 - $16,800	$250 - $15,000	$100 - $2,900	$50 - $3,500	$2300 - $44,600
Cost Recovery	Full	Partial	Partial	Partial	Full

[18] Environment Canada – New Substances Fees Regulations (SOR/2002-374) http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=59 accessed 3 Oct 2014.

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

The Productivity Commission in its *2008 Chemicals and Plastics Regulation Research Report* 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.

The scope of the 2011 review was focused specifically on the role of National Industrial Chemicals Notification and Assessment Scheme (i.e. the Scheme) in relation to the assessment and regulation of industrial chemicals. Therefore this RIS does not address the institutional and regulatory arrangements for chemicals more broadly[19],

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

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

Further detail on each of the problems is described below.

Assessment framework does not sufficiently accommodate risk

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

Stakeholders suggest that the ICNA Act unnecessarily focuses assessment effort 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:

[19] On 10 October 2014, the Council of Australian Governments agreed that SCOC would recommend a reform pathway to the regulatory framework for chemicals to improve its efficiency by the end of 2014.

- the pre-market regulatory effort does not substantially differentiate between high and low risk chemicals and the scope of the assessment is not proportionate to the level of potential 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 1,000 kg), 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 close trading partners such as New Zealand;

- post-market obligations on introducers are not clearly defined or aligned to risk;

> *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, or its secondary notification conditions.*
> *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 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 prescriptive, resource intensive and lengthy. For example, the information requirements, contents of the assessment report and assessment process are prescribed in the legislation. Consequently, 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 41 assessments of PECs covering around 106 chemicals[20].*

Legislative requirements create inefficient regulatory processes

The ICNA Act is very prescriptive in its 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 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.*

[20] unpublished data provided by NICNAS

- 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's ability to identify non-compliance is limited under the ICNA 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. NICNAS's non-compliance casework is generated through self-reporting, third party allegations, audits and internal checks.

> *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 nor is publicly available. Reliance on voluntary provision of such information creates uncertainty in assessment outcomes.*

- NICNAS's ability respond in an appropriate manner to non-compliance is also limited under the ICNA Act. Specifically, NICNAS is limited to either working with the introducers to remedy the breach within agreed timeframe or seeking prosecution through a Court (ICNA Act – Part 4 Section 8).

> *Stakeholders expressed the view that NICNAS's compliance tools are currently not proportionate to the risks posed through non-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's 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. 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 RIS 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 reliance on industry to voluntarily comply with any NICNAS recommendations (discussed below).

> *For example, there was incomplete uptake of NICNAS's recommendations by risk management agencies some 6 years after the 2006 NICNAS PEC assessment of formaldehyde. Community stakeholders considered that the environment, workers and the public had most likely been (and continued 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.*
> *Between 2011 and 2013, NICNAS issued 338 certificates for new chemicals. Of these, NICNAS recommended that risk management measures be implemented by risk management agencies for 86 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 follows 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 is able to be identified as the appropriate risk management agency;

> *For example, following a new chemical assessment involving a construction sealant, NICNAS identified volume recommendations (for conditions to be applied) to minimise cumulative environmental impacts 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, even if 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;

> *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).*

and

- 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.*

Part E: The desired objectives

The primary objective of the reform of the ICNA Act is to refocus the efforts of the NICNAS on higher risk chemicals. The role of NICNAS, which is to assess the human health and environmental risks of chemicals, will not change as part of this reform.

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

- retain NICNAS's role to assess the human health and environmental risks of industrial chemicals, while refocusing its efforts on high risk chemicals;

- better align NICNAS's regulatory effort with the anticipated risk of the industrial chemical. That is, the regulatory effort is proportionate to the level of regulatory concern about a chemical;

- address regulatory inconsistencies and uncertainty where these:

  - 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;

- 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 case for Government Intervention

The Productivity Commission in its 2008 *Chemicals and Plastics Regulation Research Report*[21] (pp.54-55) highlights three principal drivers for the need for government intervention in the hazard and risk assessment process:

1. the potential for information failures as there are only limited incentives for introducers to make this information available, or to more fully assess the risks to third parties of using the chemical
2. the public-good element of information provision are related to the extent to which it is disseminated, assessment agencies typically make this information freely available, except where there may be confidentiality concerns
3. independence of assessment ensures the integrity of assessment and safeguards the public interest

Further, the Productivity Commission noted that there are advantages in having chemical assessments undertaken at the national rather than jurisdictional level, with a single national body able to make better use of the limited supply of technical expertise needed to undertake assessments and avoids the costs to suppliers and users of different assessments in individual jurisdictions.

The Productivity Commission considered these principal drivers provide a basis for some form of regulatory intervention, noting that the regulatory arrangements are still able to make use of market mechanisms or private sector involvement to improve the efficiency of the process.

The use of international risk assessment materials

The reform of industrial chemical regulation will be consistent with the Australian Government's *Industry Investment and Competitive Agenda*, announced on 14 October 2014. The guiding principle of this agenda is that regulators should not impose any additional requirements for approvals in Australia where trusted international standards and risk assessments already exist, and approvals have already been granted, unless there is a good reason to do so.

Australia actively engages internationally on the development and application of chemical risk assessment materials. For example, NICNAS

[21] Productivity Commission Research Report: Chemicals & Plastics Regulation, July 2008. Online reference: http://www.pc.gov.au/__data/assets/pdf_file/0017/82331/chemicals-plastics-regulation.pdf

is currently working with the Organisation for Economic Cooperation and Development (OECD) and other member countries and stakeholders to cooperatively assess the hazards of industrial chemicals to generate OECD-agreed assessments and standardisation of processes internationally. International engagement assists NICNAS in ensuring that multilateral initiatives are in step with Australia's needs. NICNAS processes are benchmarked against the latest international developments concerning alternative testing methods. NICNAS is also involved in international activities which aim to avoid duplication by sharing assessment schedules of existing chemical assessments of different regulatory schemes on the eChemPortal.

Despite these efforts, regulatory frameworks for the assessment and approval of new industrial chemicals considerably vary, as detailed in this document in Part C International Comparison.

Given Australia's involvement internationally in chemical risk assessments, there are a number of factors that establish the case for an Australian risk assessment (either by government or a self-assessment by introducers) rather than automatic entry for such chemicals into the Australian marketplace.

Firstly, not all chemicals in use overseas have been assessed to determine their risk to human health and the environment, (see Part C International Comparison for further details). Similarly to Australia, overseas regulators have "grand-parented" chemicals onto their national inventories, without assessment. Acceptance of these unassessed chemicals can potentially present risks to the Australian people and the environment (i.e. a lack of evidence of harm does not imply no risk, especially for chronic harms).

Secondly, most internationally conducted risk assessments are neither publicly available nor made available to NICNAS. Acceptance of an international risk assessment outcome without access to the basis on which any decisions were made (such as the assumptions regarding exposure) may result in a lessening of the protection of Australian people and their environment. Equally, existing risk management agencies often require this information to determine whether actions are required.

Thirdly, each jurisdiction has its own unique risk management framework. For example, no other country has the equivalent of Australia's poisons scheduling arrangements, which are a product of our federal structure and history. Even where NICNAS has access to an international risk assessment, any recommended risk management controls (where relevant in the Australian context) need to be adapted to the Australian risk management system (for public health, work health and safety, or environmental risk management, which are usually undertaken by states and territories). Simply adopting international risk management

determinations, without consideration of Australian uses and exposures or the Australian risk management framework is not likely to result in the required level of risk mitigation. Additionally, this may introduce inefficiency if risk managers are required to identify and acquire information necessary to inform risk management decisions.

Significant constraints (and in some circumstances, risks) are associated with acceptance of overseas determinations (including approvals, bans and restrictions). Risk determinations can vary between countries based on:

- Political/policy considerations – e.g. Canada has been less restrictive than Australia on asbestos for many decades, to minimise the impact on its mining industry;
- Institutional arrangements – regulatory system variations that guide risk management. For example, determinations overseas may be based on extensive post-market bio-monitoring systems that can quickly detect harms. Australia does not have such systems;
- Infrastructure variations – some countries have access to high temperature incineration for quick and easy disposal of toxic waste. Australia has landfill and waterway effluent treatment options;
- Environmental conditions – unique environmental conditions (eg temperature, rainfall) across countries lead to varying risk management restrictions in those countries;
- The use pattern of a chemical may vary between countries. Determinations (including restrictions or bans) based on the use pattern in one country may not directly apply to the chemical in another, where it may have a different use pattern; and
- The scope of assessment is determined by governing legislation and can differ between countries. For example, some countries do not consider risks to worker safety or to the environment in their determinations. A reduction in scope through the adoption of these determinations may lead to unknown risks to, and inadequate safeguarding of the Australian population or environment.

The Australian Government is committed to ensuring the competitiveness and productivity of our industries; however, the challenge for the chemical industry is balancing this priority with the need to safeguard human health and the environment. International determinations and risk assessments should be considered, taking account of relevant circumstances such as use, exposure and disposal scenarios. Through its work with OECD, Australia accepts international hazard assessments materials, placing greatest regulatory weight on hazards assessments that meet OECD standards.

Therefore, while the case for an Australian risk assessment has been established, there is still significant scope to utilise international risk assessments materials, particularly the hazard assessment components,

to reduce the burden on industry globally whilst maintaining protection of public health and the environment. Each of the Options 2-4 involves the use of international data and assessments materials to varying degrees.

The options

As the case for Government intervention in the use of industrial chemicals to safeguard public health and the environment is well established and supported by key stakeholders, non-regulatory options are not considered.

The objective of this reform is to refocus NICNAS's assessment efforts on higher risk chemicals, by introducing risk stratification thresholds. When dealing with the introduction of a new industrial chemical, there are three clear forms of treatment approaches available for a new chemical, described in the table below.

Risk based approaches to assessment of new chemicals

Form of treatment	Class
Allow introduction with minimal or no notification requirements or pre-market assessments	1
Allow introduction following self-assessment by the introducer against criteria and notification. The agency may undertake risk based audits to ensure accuracy of self assessments	2
Allow introduction after a pre-market assessment of a new chemical	3

Option 2-4 (described in further detail below) explore how these three approaches, or Classes, could be used to achieve differing risk based approaches to new chemicals. In each option, criteria (i.e. volume, hazard or category of use) are presented that define chemicals that would fall into each class. These criteria differ across the Options as they reflect the broader focus of the Option on pre- or post-market assessment.

The four regulatory options for industrial chemicals are identified below:

Option 1: Base case – make no change to the scope or activities of NICNAS.

Option 2: Focus on post-market regulatory controls for both new and existing industrial chemicals with the assessments requirements informed by category of use and volume.

Option 3: Pre- and post-market regulatory controls for new chemicals, post-market regulatory controls for existing chemicals, with the assessment requirements informed by hazard and exposure.

Option 4: Continued focus on pre-market regulatory controls for new chemicals and post-market regulatory controls of existing chemicals, with the assessment requirements informed by category of use and volume.

The options described in the RIS, except for the base case, use different methodologies to determine risk thresholds based on treatment approaches described above. These options use a graduated risk-based approach that use different methodologies for quantifying risk (based on parameters such as category of use, volume, hazard and exposure). Aside from the base case, each of the options involves varying changes to pre-market and post-market assessment arrangements to create efficiencies in the risk assessment and management process while ensuring appropriate safeguarding of public health and the environment.

Note, chemicals that fall outside these classes (i.e. are not under the remit of the ICNA Act), include chemicals for agricultural, veterinary and therapeutic use, and those used as food or in food additives. Articles, radioactive chemicals and mixtures are not considered chemicals under the ICNA Act.

Description of the options

Option 1: Base Case – make no changes to the scope or activities of NICNAS

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 the base case.

Option 2: Focus on post-market regulatory controls for both new and existing industrial chemicals with the assessments requirements informed by category of use and volume.

This option involves the following:

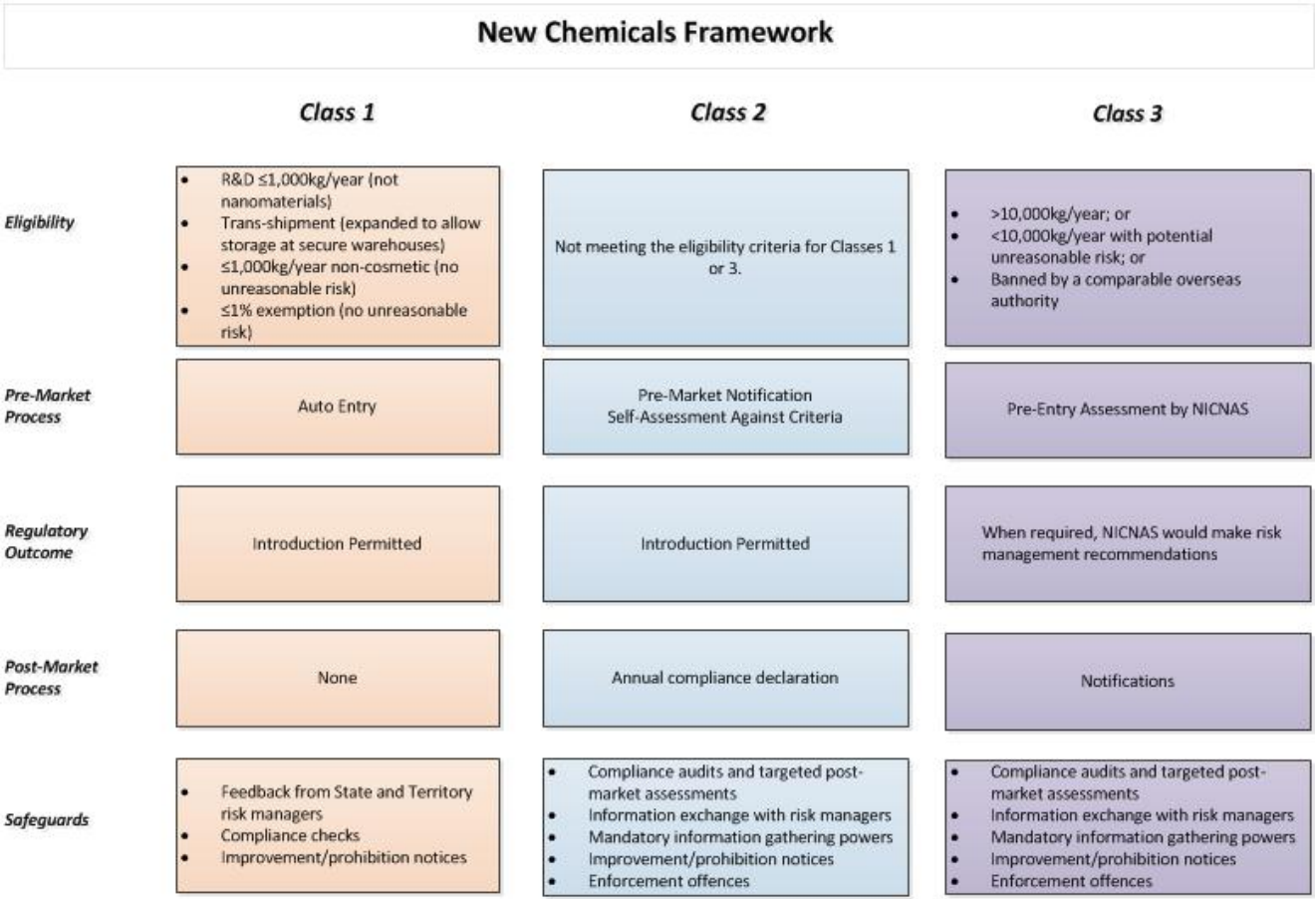
- new chemicals would be introduced into Australia following industry self-assessment, except for a small portion that pose an unreasonable risk (based on three classes of chemicals and specified eligibility criteria)
- removing prescriptive regulatory requirements for assessment of existing chemicals (for more efficient post-market assessment of those chemicals already on the market)

- removing current risk management powers and limiting NICNAS' role to risk assessment (mainly post market) and providing recommendations to risk management agencies
- providing NICNAS with contemporary compliance tools as a safeguard.

Approach to assessment of new chemicals

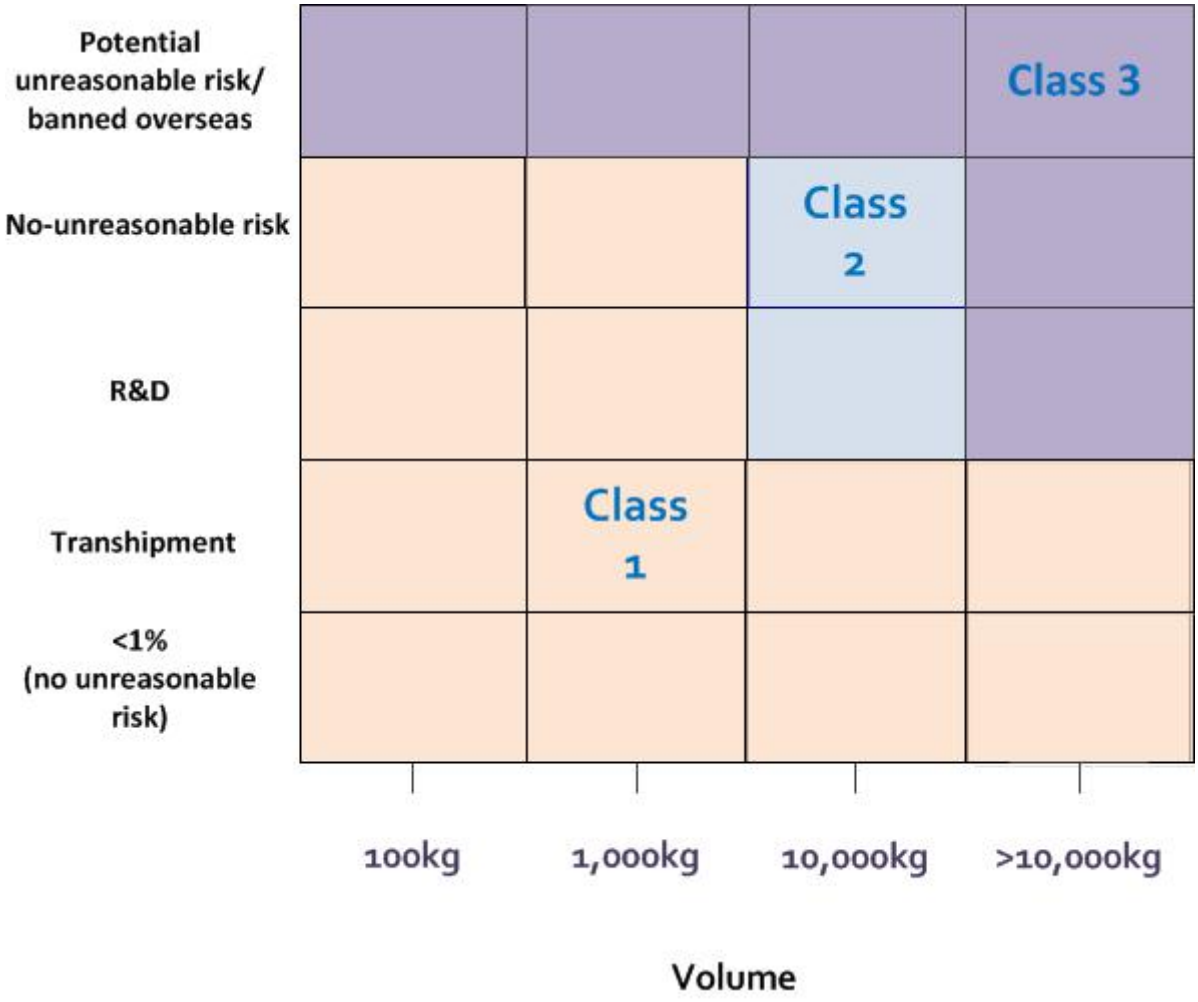
For Option 2, the classification of chemicals into three Classes is based on the parameters of category of use and exposure. The intended criteria and treatment of chemicals for each class is described in Diagram 2 below. The methodology for classifying chemicals is demonstrated in the matrix at Diagram 3, which plots hazard and exposure indicators applicable to the particular circumstances.

Diagram 2: Option 2 Class Structure



Intended criteria for each class is listed below and also demonstrated in the matrix at Diagram 3, which plots hazard and exposure indicators applicable to the particular circumstance.

Diagram 3: Option 2 Class Matrix



Under this option, new chemical introductions would involve the following:

- Reducing pre-market barriers to the introduction of new chemicals by focusing regulatory action on post-market monitoring and assessment rather than pre-market assessment by NICNAS.

Class 1: automatic entry (very low risk chemicals)

- Continuing to allow the automatic entry of chemicals that are considered very low risk, i.e. they are:
  - R&D ≤1,000 kg/year (not nanomaterials)
  - Trans-shipment (expanded to allow storage at secure warehouses)
  - ≤1,000 kg/year (no unreasonable risk)
  - ≤1% exemption (no unreasonable risk)

- Acknowledging that the use of chemicals in this class is subject to existing state and territory regulation, these chemicals will not be subject to pre-entry notification or assessment requirements, or post-market annual reporting requirements

- Strengthening NICNAS's post-market monitoring powers such that companies are required to keep records and may be audited by NICNAS.

Class 2: self-assessment and notification (medium risk chemicals)

- Significantly expanding the chemicals subject only to notification to NICNAS on introduction (following self-assessment against risk-based criteria – for example, <10,000kg/year with no unreasonable risk).

- The use of international assessments would be increased in this option through the inclusion in Class 2 of certain chemicals assessed by comparable overseas regulatory authorities for the same use in Australia and that any risk management conditions overseas are complied with by the Australian introducer. Self-assessments would need to take into consideration Australian exposure variables.

- This would result in 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.

- Safeguarding of public health and the environment would be achieved through post-market monitoring powers that support an active audit program (risk screening and assessment) for all Class 2 chemicals.

Class 3: notification and pre-market assessment (highest risk chemicals)

- Retaining the capacity for NICNAS to undertake a detailed assessment for those chemicals that are likely to pose a high risk. Chemicals subject to pre-market assessment would be those with the following attributes:
  - >10,000kg/year; or
  - <10,000kg/year with potential unreasonable risk; or
  - Banned/prohibited by a comparable overseas authority.

- Removing the capacity for NICNAS to impose any controls (e.g. volume use, time, location) on new chemicals, but NICNAS would retain the capacity to make recommendations to risk management agencies.

- Requiring NICNAS to publish a summary of the assessment of each Class 3 chemical on its website. The summary would include:
  - the name by which the chemical is known (and/or the proper chemical name if an application was not made and granted for this to be treated as exempt information);
  - the use of the chemical (this may be expressed generally); and
  - any recommendations made to risk management agencies.

Compliance

- Consistent with removing NICNAS's power to impose conditions of use for new chemicals (i.e. removal of permits, removal of annotation of AICS), any conditions of the use of existing chemicals (other than particulars of use) would be removed.

- However, improvement notices may be issued by NICNAS to an introducer requiring compliance with the introducer's notification (including any comparable overseas authority conditions of use relied upon to ensure no unreasonable risk).

- Strengthening NICNAS's compliance tools to take action in the event of non-compliance. This would include:

  - enabling NICNAS to require introducers (i.e. regulated entities) to produce information;
  - enabling improvement notices to be issued in response to non-compliance with introduction notifications and classifications; and
  - aligning any offence provisions with similar Australian Government regulatory frameworks.

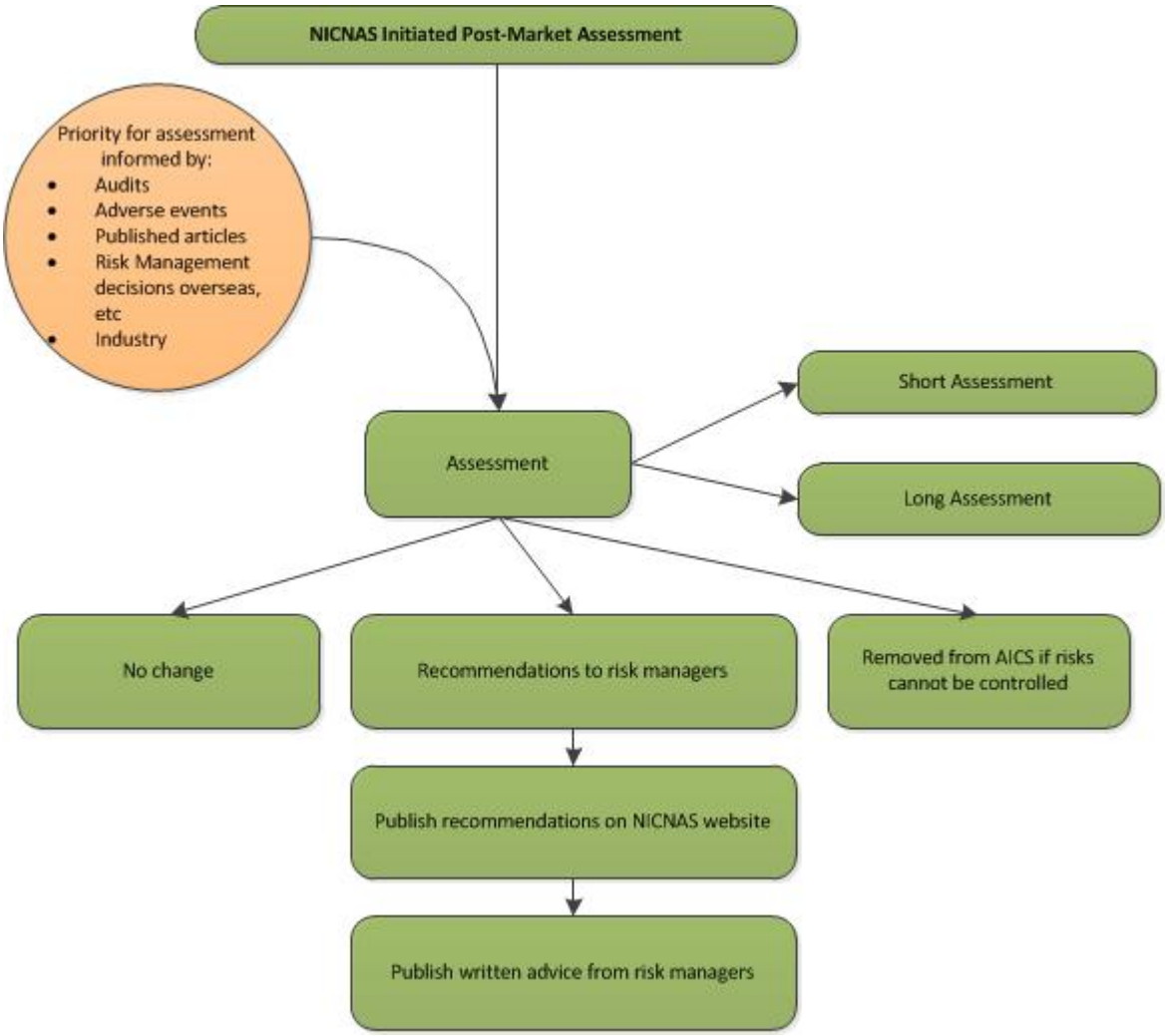
Existing chemicals and post-market assessments

- Providing for NICNAS to commence an assessment of a Class 1 or Class 2 chemical, a chemical on AICS or reassessment of a previously assessed chemical in response to information arising from advice from introducers, risk managers, other stakeholders or as a result of the outcomes of audits or adverse events.

- Providing NICNAS with the ability to tailor the scope and extent of an assessment to the particulars of the existing chemical being assessed and the nature of the concern. Assessments may result in no change, new recommendations to risk managers or removal of the chemical from AICS (with agreement of one or more risk managers).

The proposed process for NICNAS initiated assessment is reflected in Diagram 4.

Diagram 4: Option 2 Existing Chemicals NICNAS Initiated Assessments



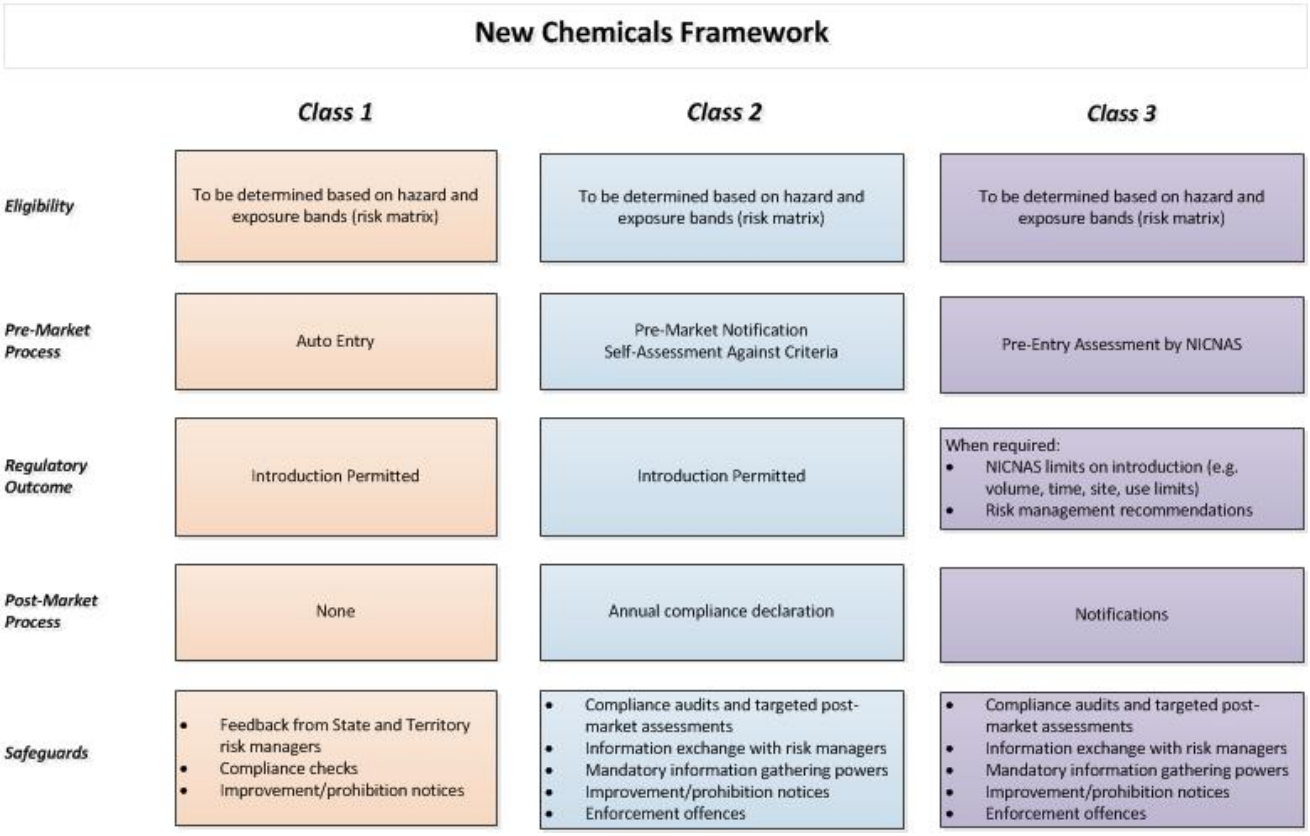
Option 3: Pre- and post-market regulatory controls for new chemicals, post-market regulatory controls for existing chemicals, with the assessment requirements informed by hazard and exposure

This option involves the following:

- As with Option 2 and 4, there would be three classes of industrial chemicals, this time based on indicative risk[22], and each with different pre- and post-market requirements. See Diagram 5 below.

Whilst more complex than Option 2 and 4, structuring the classes around the indicative risk associated with the proposed use of the chemical, based on a consideration of the intrinsic hazard associated with a chemical and the anticipated exposure, would be expected to focus more accurately regulatory effort on chemicals that would potential pose a greater risk to human health and the environment whilst reducing the regulatory burden for chemicals which would not cause such concern due either to their hazard or nature of the intended use.

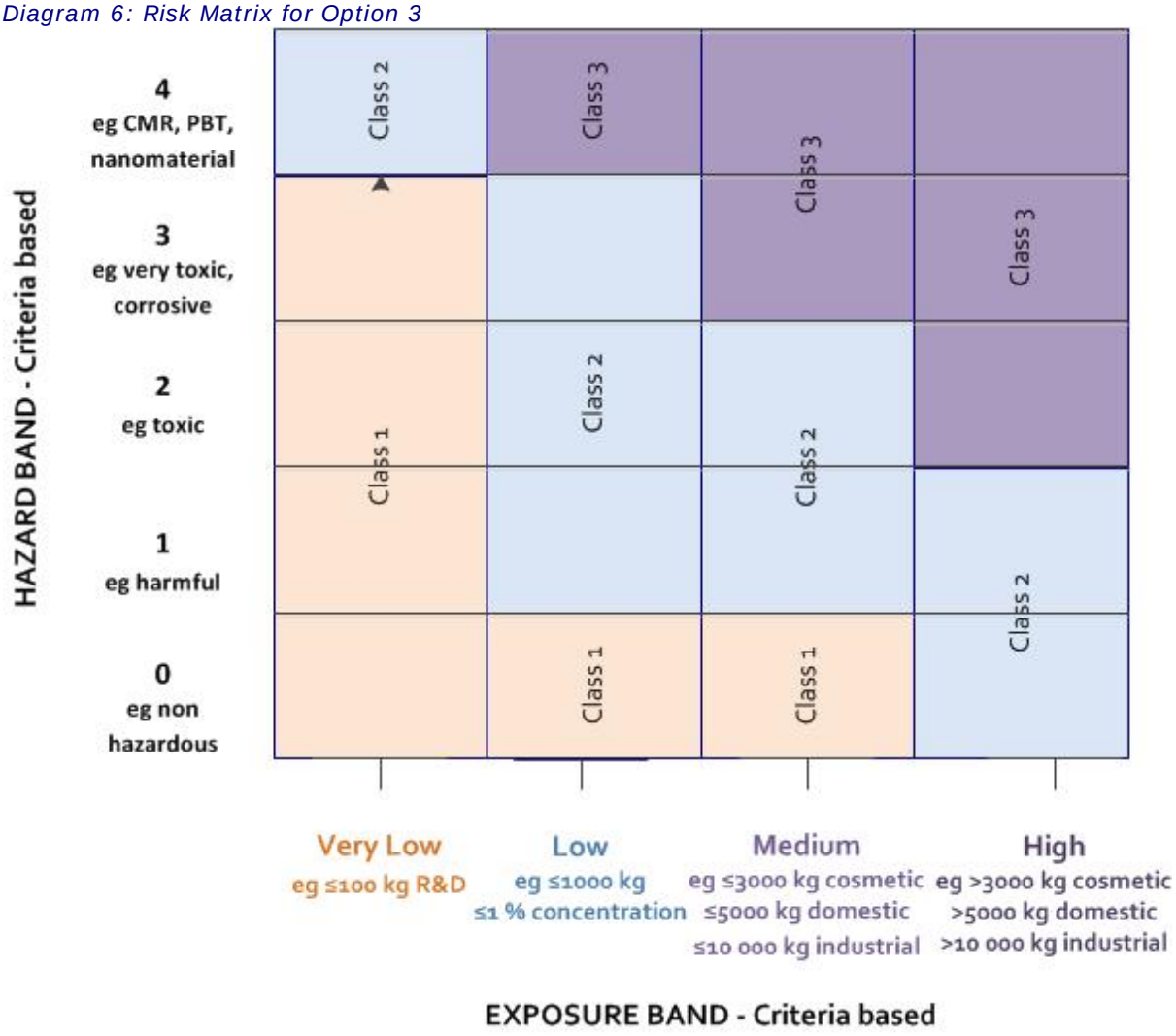
Diagram 5: Option 3 Class Structure



[22] Indicative risk is the level of risk suggested by the application of the Indicative Risk Matrix on page 48.

Eligibility for Classes 1 to 3 would be determined based on a risk matrix (see Diagram 6 below) that plots hazard and exposure indicators applicable to the particular circumstance. Intended criteria for hazard and health exposure bands are listed below, and also shown in Diagram 6.

Diagram 6: Risk Matrix for Option 3



The Hazard Band table below outlines intended criteria for hazard bands 0 to 4. These criteria are presented here to provide the reader with an understanding of the proposed approach to the use of hazard bands in the risk matrix.

Table 3: Hazard bands and draft indicative criteria

Note: definitions used in this table are defined at the end of the table

<table>
<tr><th>HAZARD BAND</th><th>DRAFT INDICATIVE CRITERIA FOR HAZARD BAND</th></tr>
<tr><td>0</td><td>

All indicators fall outside the criteria listed in hazard bands 1-4.
Non-hazardous chemical for human health and environment.
Not a dangerous good.

Human Health criteria:
LD50 >2000 mg/kg bw (acute toxicity, oral and dermal routes of exposure)
LC50 >20 mg/L (acute toxicity, inhalation route of exposure)
Non-irritant
Non-sensitising
Non-carcinogenic, non-mutagenic, non-reproductive/developmental toxicity, non-neurotoxic

Environmental criteria:
Not toxic to fish (LC50/EC50 is >100 mg/L), and
Not toxic to aquatic invertebrates (LC50/EC50 is >100 mg/L), and
Not toxic to algae (LC50/EC50 is >100 mg/L); and

Be readily biodegradable; and

At least one of the following:

Dissolves in water without dissociation or association and is not surface active and the partition coefficient (n-octanol/water) at 20°C, as log P_{ow} does not exceed 3; or
Solubility in water is greater than 1 mg/L; or
The molecular weight (for non-polymers) or number-average molecular weight (for polymers) is greater than 1000.

</td></tr>
<tr><td>1</td><td>
<table>
<tr><th colspan="2">Acute Toxicity—Harmful according to the GHS</th></tr>
<tr><td>Route of exposure</td><td>Test values</td></tr>
<tr><td>Oral</td><td>LD50 >300 and ≤2000 mg/kg bw</td></tr>
<tr><td>Dermal</td><td>LD50 >1000 and ≤2000 mg/kg bw</td></tr>
<tr><td>Inhalation</td><td>LC50 >10 and ≤20 mg/L (vapour)</td></tr>
<tr><th colspan="2">Irritant (reversible damage)</th></tr>
<tr><td>Dermal irritation</td><td>GHS: Substances which cause significant inflammation of the skin that persists to the end of the observation period of normally 14 days
OR
Structural alert: e.g. alpha alkyne, esters (including acrylic and methacrylic esters)</td></tr>
<tr><td>Ocular irritation</td><td>GHS: Substances inducing eye irritant effects reversing within an observation period of 7 days
OR
Structural alert: e.g. aliphatic alpha hydroxyesters</td></tr>
</table>
PLC: Polymers that meet PLC criteria.

Environmental criteria:
GHS: Substances that align with the criteria for:

H402: Harmful to aquatic life
H412: Harmful to aquatic life with long lasting effects
H413 May cause long lasting harmful effects to aquatic life

</td></tr>
</table>

<table>
<tr><th>HAZARD BAND</th><th>DRAFT INDICATIVE CRITERIA FOR HAZARD BAND</th></tr>
<tr><td></td><td>Biodegradability of Y %* in 28 days or BAF <Z1, BCF <Z2*
Solubility or release to waterways*
* Actual values to be determined.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th colspan="2">Harmful chronic/repeat dose toxicity according to the GHS</th></tr>
<tr><th>Route of exposure</th><th>Test values</th></tr>
<tr><td>Oral</td><td>LOAEL >10 mg/kg bw and ≤100 mg/kg bw/d</td></tr>
<tr><td>Dermal</td><td>LOAEL >20 mg/kg bw/d and ≤200 mg/kg bw/d</td></tr>
<tr><td>Inhalation</td><td>LOAEC >50 and ≤250 mg/L/6-hr/d (gas)
LOAEC >0.2 and ≤1.0 mg/L/6-hr/d (vapour)
LOAEC >0.02 and ≤0.2 mg/L/6-hr/d (dust/mist/fume)</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td>If no data available, use structural alert</td><td>Structural alert: e.g. hindered amines, alkoxy silane, nickel compounds, boron compounds, organotins</td></tr>
<tr><th colspan="2">Skin sensitiser</th></tr>
<tr><td>Dermal sensitisation</td><td>GHS: A substance that will lead to an allergic response following skin contact
OR
Structural alert: e.g. formaldehyde donors, alpha-lactams, beta-lactams</td></tr>
</table>

Environmental criteria:
GHS: Substances that align with the criteria for:
• H401: Toxic to aquatic life
• H411: Toxic to aquatic life with long lasting effects
Biodegradability of Y %* in 28 days or BAF <Z1, BCF <Z2*
Solubility or release to waterways*
* Actual values to be determined.
</td></tr>
<tr><td>3</td><td>
<table>
<tr><th colspan="2">Acute toxicity-Very Toxic/Toxic according to the GHS</th></tr>
<tr><th>Route of exposure</th><th>Test values</th></tr>
<tr><td>Oral</td><td>LD50 ≤300 mg/kg bw</td></tr>
<tr><td>Dermal</td><td>LD50 ≤1000 mg/kg bw</td></tr>
<tr><td>Inhalation</td><td>LC50 ≤10 mg/L (vapour)</td></tr>
<tr><th colspan="2">High chronic/repeat dose toxicity according to the GHS</th></tr>
<tr><th>Route of exposure</th><th>Test values</th></tr>
<tr><td>Oral</td><td>LOAEL ≤10 mg/kg bw/d</td></tr>
<tr><td>Demal</td><td>LOAEL ≤20 mg/kg bw/d</td></tr>
<tr><td>Inhalation</td><td>LOAEC ≤50 ppm/6-h/d (gas)
LOAEC ≤0.2 mg/L/6-hr/d (vapour)
LOAEC ≤0.02 mg/L/6-hr/d (dust/mist/fume)</td></tr>
<tr><th colspan="2">Corrosive (irreversible damage)</th></tr>
<tr><td>Dermal corrosion</td><td>GHS: A substance that produces destruction of skin tissue, namely visible necrosis through the epidermis and into the dermis
OR
Structural alert: e.g. (meth)acrylic acids, substituted benzoic acid halogenides</td></tr>
<tr><th colspan="2">Respiratory sensitiser</th></tr>
</table>
</td></tr>
</table>

HAZARD BAND	DRAFT INDICATIVE CRITERIA FOR HAZARD BAND	
	Respiratory sensitisation	**GHS**: Substance that will lead to hypersensitivity of the airways following inhalation of the substance OR **Structural alert**: e.g. acid anhydrides, isocyanates

Environmental criteria:

GHS: Substances that align with the criteria for:

- H400: Very toxic to aquatic life
- H410: Very toxic to aquatic life with long lasting effects

Biodegradability of Y %* in 28 days or BAF <Z1, BCF <Z2*

Solubility or release to waterways*

* Actual values to be determined.

HAZARD BAND		
4	**Carcinogenic**	**GHS:** A substance or a mixture which induces cancer or increases its incidence OR **Structural alert:** e.g. polycyclic aromatic hydrocarbons, halogenated benzene, alkyl nitrite
	Mutagenic	**GHS:** Chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny OR **Structural alert**: e.g. acrylamides, dichlorobenzidine based pigments
	Reproductive/Developmental toxicity	**GHS**: Chemicals that cause adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring OR **Structural alert**: e.g. vinyl esters, ethylene glycol ethers, epoxides, boron compounds
	Neurotoxicity	**GHS:** Substances that damage or destroy the tissues of the nervous system, especially neurons, the conducting cells of the body's central nervous system OR **Structural alert**: e.g. vinyl esters

Environmental criteria:

Substances listed on International Conventions or possess characteristics similar to those chemicals.

Substances that meet the national PBT criteria, namely:

Persistent (P): $t_{1/2}$ air >2 days
$t_{1/2}$ water >2 months
$t_{1/2}$ soil >6 months

HAZARD BAND	DRAFT INDICATIVE CRITERIA FOR HAZARD BAND	
		$t_{1/2}$ >6 months
	Bioaccumulative (B): or BMF > 1	BCF or BAF ≥2000 or log K_{ow} ≥4.2; or log K_{pa} >6 and log K_{ow} ≥2;
	Toxic (T):	Category Chronic 1 under long term aquatic hazard of the GHS classifications (NOEC ≤0.1 mg/L); OR *if chronic data unavailable* Category Chronic 1 based on acute toxicity of the GHS classifications (LC50 or EC50 ≤1.0 mg/L).
	Uncertainty: substances	Nanomaterials, endocrine disrupting chemicals, perfluorinated

Definitions:

BAF means the bioaccumulation factor, which is the ratio of the chemical concentration in an organism or biota to the concentration in water, in situations where both the organism and its food are exposed to the substance.

BCF means bio-concentration factor, which is the ratio of the chemical concentration in an organism or biota to the concentration in water, in situations where the organism is exposed through the water only.

BMF means the biomagnification factor, which is the ratio of the concentration of a chemical in a predator organism at a particular trophic level to the concentration of the chemical in the issue of its prey organism at the next lowest trophic level for a given body of water and substance exposure.

EC50 means half maximal effective concentration and refers to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.

ECX means effective concentration for X % of the test population.

GHS means Globally Harmonized System of Classification and Labelling of Chemicals.

LC50 means median lethal concentration (lethal concentration, 50%) of a toxin, radiation or pathogen required to kill half the members of a tested population after a specified test duration.

LD50 means median lethal dose (lethal concentration, 50%) of a toxin, radiation or pathogen required to kill half the members of a tested population after a specified test duration.

LOAEC means lowest-observed-adverse-effect-concentration.

LOAEL means the lowest-observed-adverse-effect level, which is the lowest concentration or amount of a substance found by experiment or observation that causes an adverse alteration of morphology, function, capacity, growth, development, or lifespan of a target organism distinguished from normal organisms of the same species under defined conditions of exposure.

NOEC means no observed effect concentration, which is a measure of pollutant concentration that is used to determine risk assessment in public health.

The Exposure Band table below outlines intended criteria for Exposure Bands very low to high or uncertain. These criteria are presented here to provide the reader with an understanding of the proposed approach to the use of exposure bands in the risk matrix.

Table 42: Exposure bands and draft indicative criteria

EXPOSURE BAND	INDICATIVE CRITERIA FOR EXPOSURE BAND
Very low	Research & Development only ≤100 kg Transhipment
Low	For all uses: Volume ≤1000 kg OR Concentration ≤1 % in a product Research & Development >100 kg
Medium	Volume ≤3000 kg cosmetic/personal use Volume ≤5000 kg domestic use Volume ≤10,000 kg all other uses
High or uncertain	Not meeting criteria for very low, low or medium exposure bands

Notes:

Domestic use means 'general exposure' where chemical is used in household domestic mixtures or products, or in articles where a significant proportion of the chemical is intended to be released during normal use (e.g. cleaning product).

Cosmetic / personal use means 'intentional exposure' whereby the mixture or product is intended solely for direct application onto the human body including the skin, hair, nails, lips, teeth and mouth generally for cleaning, perfuming or protection (e.g. personal care product).

Based on the application of the risk matrix, chemicals can be identified as fitting into any of three classes. The regulatory requirements for each class are outlined below.

Class 1: Very Low Risk Chemicals

- Allowing the automatic entry of chemicals that are considered very low risk, i.e. they meet prescribed hazard and exposure criteria making them eligible for Class 1.

- Acknowledging that the use of chemicals in this class is subject to existing state and territory regulation, these chemicals will not be subject to pre-entry notification or assessment requirements, or post-market annual reporting requirements. However, introducers would be required to keep records and be subject to compliance checks by NICNAS as necessary.

Class 2: Low Risk Chemicals

- Allowing introduction of chemicals immediately following self-assessment and pre-entry notification to NICNAS of chemicals that are considered to be relatively low risk because of either their hazard characteristics or proposed use. These chemicals must meet prescribed hazard and exposure criteria making them eligible for Class 2.

- The use of international assessments would be increased in this option through the inclusion in Class 2 of new chemicals based on the assessment by a comparable agency where the use of the chemical is the same and the volume is the same or lower as that assessed overseas, and the introducer complies with any conditions recommended by the overseas regulator (e.g. conditions not to use the chemical in a consumer spray formulation or above a certain concentration).

- The use of international data would also be increased by allowing introducers to use international information (including industry self-assessed classifications e.g. REACH, CLP databases) to determine the chemical class, without the need for the introducer to hold the original study data. The introducer would be required to ascertain any permission required by the data owner to use such information.

- Requiring pre-market notification (only) of such chemicals to include:
  - the name by which the chemical is commonly known
  - the proper chemical name (i.e. CAS or IUPAC name)
  - CAS Number (where available)
  - hazard classification and/or hazard information
  - the proposed volume to be introduced
  - the proposed use for the chemical

- Requiring introducers to submit an annual compliance declaration to NICNAS to confirm that the class criteria and information provided in the pre-market notification continue to be met by the introduced chemical/s.

- Providing NICNAS with the ability to audit a proportion of pre-market notifications annually to validate that the hazard and exposure assessment is consistent with Class 2 criteria and ensure that introducers are compliant with their notifications.

Class 3: Medium-High Risk Chemicals

- Requiring all chemicals not meeting hazard and exposure criteria for Classes 1 or 2 to be notified to and assessed by NICNAS pre-market. These chemicals would be considered to be of medium or high indicative risk, or be associated with significant uncertainty as to the level of risk that the chemicals may pose (i.e. information gaps).

- Providing NICNAS with the ability to screen applications to determine whether sufficient information is present to conduct a risk assessment (within a statutory period). If there is not sufficient information:
  - NICNAS would provide the notifier a period of time within which to provide the necessary information.
  - The timeframe will be paused (i.e. 'stop the clock') during any time that NICNAS is awaiting information from the notifier.
  - The application would be considered withdrawn by the notifier if the information was not submitted within the required/agreed timeframe.

- Streamlining the pre-market assessment approach to better utilise international use and exposure data (where it is appropriate and reliable in the Australian context).

- The scope and extent of the pre-market assessment and corresponding data requirements to be based on indicative risk i.e. hazard and exposure bands.

- Requiring the issuance of an assessment certificate prior to the introduction of these chemicals. The regulatory outcome of an assessment could result in the:
  - issuing of a certificate with or without particulars of use (i.e. extent of the risk assessment undertaken) and conditions of use (such as annual volume, sites of use, time-limited certificate) on introduction; or
  - refusal to issue a certificate[23] if the risks cannot be managed, either by conditions of introduction, or by the imposition of risk management conditions by risk management agencies.

- Providing for all certificates to be subject to conditions similar to the existing secondary notification conditions. Specifically, introducers would be required to notify NICNAS on becoming aware of changes (after the date of the assessment was issued) that significantly change the level or nature of risk of the chemical.

- Establishing processes that provide for consultation with the proposed risk manager in relation to the adequacy of risk mitigation measures and the issuing or refusal of a certificate.

[23] In consultation with the appropriate risk management agencies.

- Requiring NICNAS to publish a summary of the assessment of each Class 3 chemical on its website. The summary would include:
  - the name by which the chemical is known (and/or the proper chemical name if an application was not made and granted for this to be treated as exempt information);
  - 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.

Compliance

- NICNAS would be able with the ability to audit (undertake risk screening and assessments as needed) a proportion of notifications annually to ensure that introducers are compliant with their notifications.

- Should any change in risk/s be identified by NICNAS or jurisdictional regulators for a chemical introduced as a Class 1, Class 2, or Class 3, NICNAS may review its eligibility for further introduction under that class.

- NICNAS would have access to more contemporary tools to ensure compliance with the introducers obligations under the ICNA Act – Specifically:
  - aligning any offence provisions with similar Australian Government regulators;
  - enabling improvement notices and prohibition notices to be issued in response to non-compliance;
  - enabling NICNAS to require introducers (i.e. regulated entities) to produce documents; and
  - enabling NICNAS to revoke a certificate as necessary before a chemical is listed on AICS.

Assessment of Existing Chemicals and Post-Market Assessment

- Allowing NICNAS to commence an assessment of an existing chemical, a chemical introduced under Class 1 or 2 (post market audits), or a re-assessment of new chemical in response to a request to vary a certificate or particulars or conditions of use of a chemical on AICS or on NICNAS's own initiative.

- Replacing the prescriptive PEC process by providing NICNAS with the ability to tailor the scope and extent of an assessment to the particulars of the existing chemical being assessed and the nature of the concern. Assessments may result in no change, changes to particulars of use, limitations of use on AICS, or removal of the chemical from AICS.

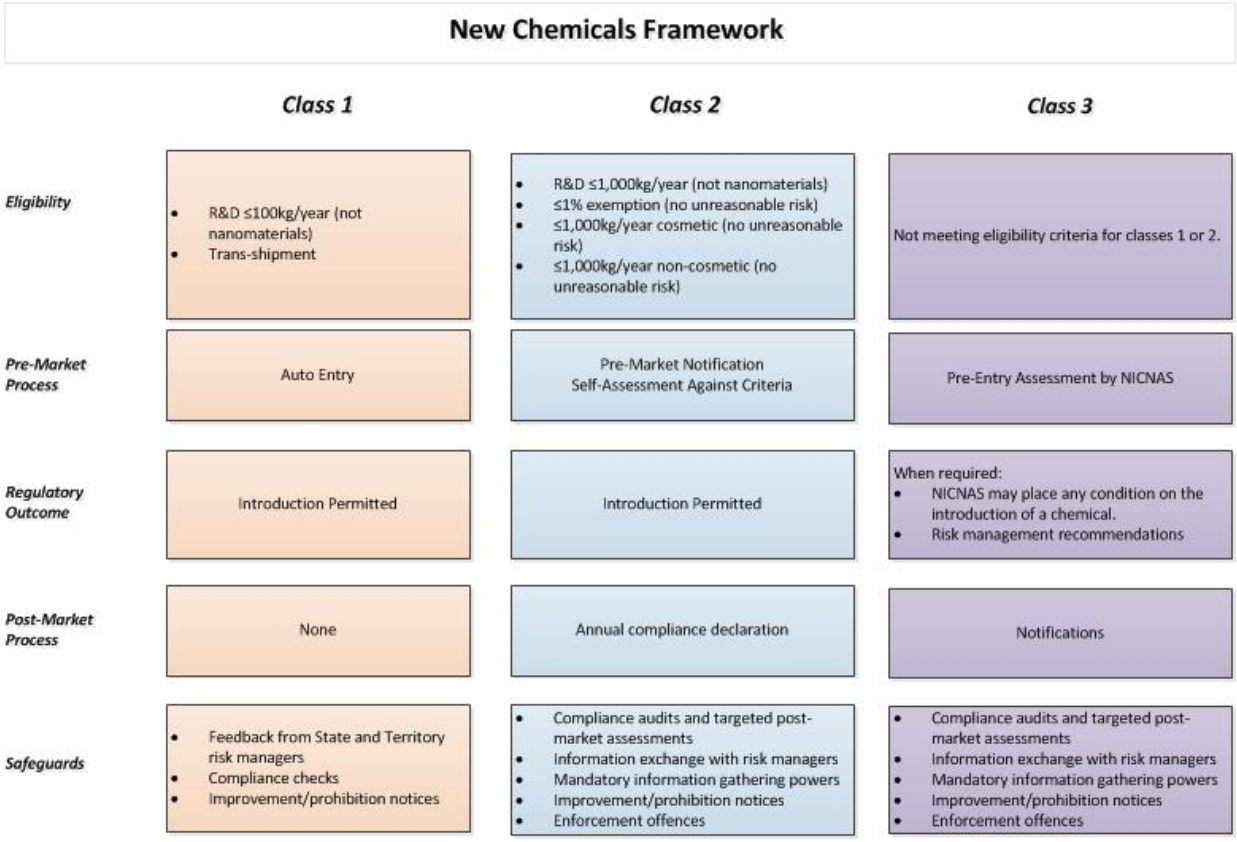
Option 4: Continued focus on pre-market regulatory controls for new chemicals and post-market regulatory controls of existing chemicals, with the assessment requirements informed by category of use and volume

This option would focus 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 self-assessment and pre-market notification (only), but with the default position being pre-market assessment by NICNAS

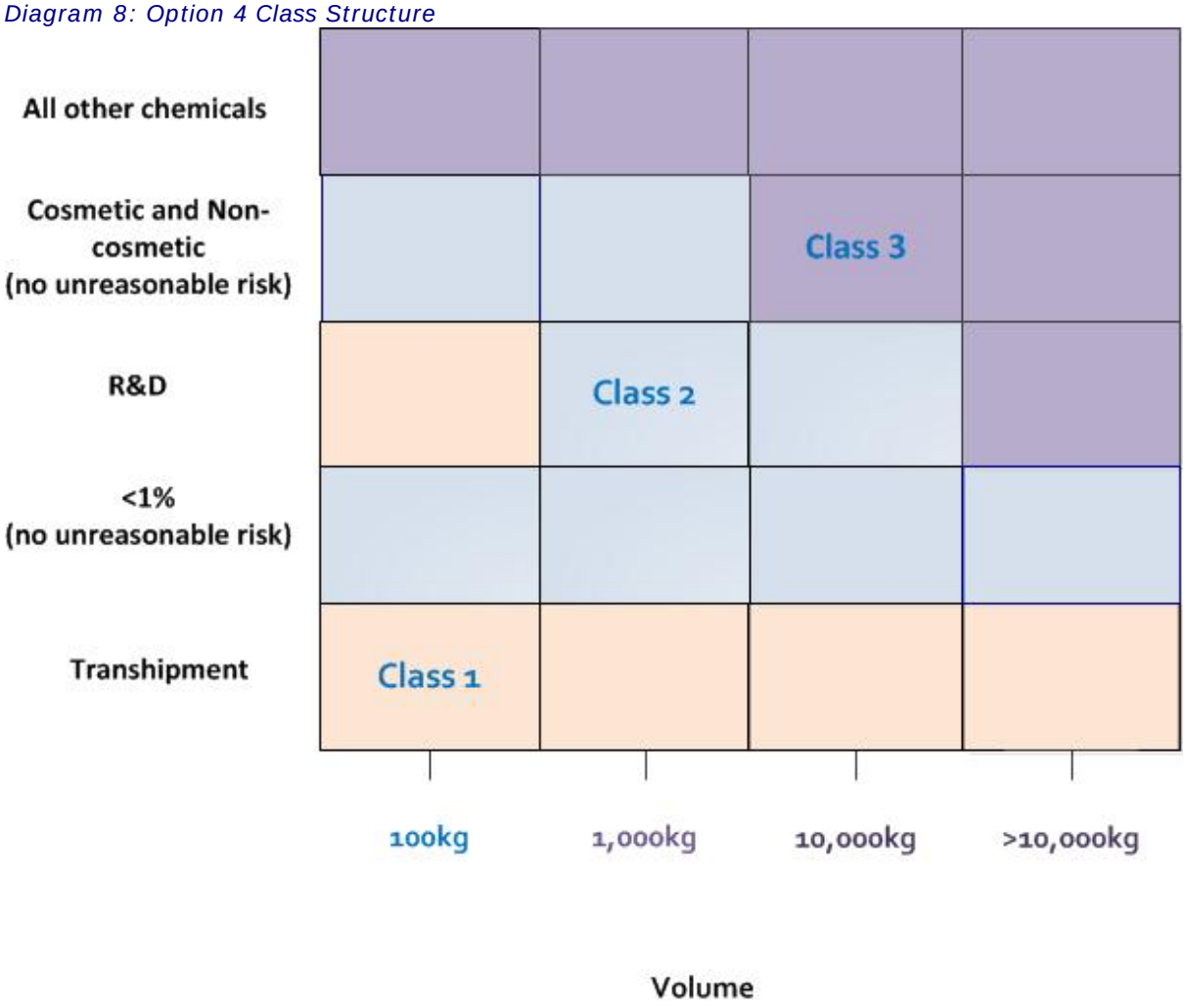
- As with Options 2 and 3, there would be three classes of industrial chemical (see diagram 7).

Diagram 7: Option 4 Class Structure



Intended criteria for each class in Option 4 are listed below and also demonstrated in the matrix at Diagram 8, which plots hazard and exposure indicators applicable to the particular circumstance.

Diagram 8: Option 4 Class Structure



Class 1: Very Low Risk Chemicals

- Continuing to allow the automatic entry of chemicals that are considered very low risk, i.e. they are:
  - R&D ≤100 kg/year (not nanomaterials)
  - Transhipment

- Acknowledging that the use of chemicals in this class is subject to existing state and territory regulation, these chemicals will not be subject to pre-entry notification or assessment requirements, post-market annual reporting requirements or audits by NICNAS.

Class 2: Low Risk Chemicals

- Allowing the introduction following notification to NICNAS of chemicals that meet the following criteria:
  - R&D 100-1,000 kg/year (not nanomaterials); or

- ≤1% exemption (no unreasonable risk)
- ≤1,000 kg/year cosmetic (no unreasonable risk)
- ≤1,000 kg/year non-cosmetic (no unreasonable risk)

- This would include certain chemicals assessed by overseas regulatory authorities for the same use and found not to require risk management controls.

- 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.

Class 3: Medium/High Risk Chemicals

- Streamlining the pre-market assessment approach to better utilise international hazard, use and exposure data (where it is appropriate and reliable in the Australian context). Introducers would be required to provide study data on which a notification is based at the time of application to NICNAS.

- Streamlining the scope and extent of the pre-market assessment and corresponding data requirements to be based on indicative risk ie. hazard and exposure bands.

- 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 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.

- Requiring NICNAS to publish the full assessment report of each chemical assessed on its website. Introducers would be able to seek to have commercial-in- confidence material excluded from publishing however this information would be provided to relevant risk managers.

Compliance

Providing NICNAS with more appropriate compliance tools – Specifically:

- aligning any offence provisions with similar Australian Government regulators;

- 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.

Existing Chemicals and Post-Market Assessments

- Allow NICNAS to commence assessment of an existing chemical or a re-assessment of a new chemical in in response to the application of risk management controls (i.e. concentration or volume limits, use or disposal conditions, and including industry self-assessed classification) through international assessments.

- Replacing the prescriptive PEC process by providing NICNAS with the ability to tailor the scope and extent of an assessment to the particulars of the existing chemical being assessed and the nature of the concern expressed in the international assessment. Assessments may result in no change, changes to particulars of use, limitations of use on AICS, conditions on introduction or removal of the chemical from AICS.

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 self-assessment and notification, and a very limited class of chemicals subject to pre-market assessment. Those few chemicals subject to pre-market assessment by NICNAS 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's 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 4 focuses regulation on pre-market controls with limited chemicals eligible for entry based on automatic entry or self-assessment and 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;

- Unlike Options 2 and 4, Option 3 classifies new chemicals by risk based on hazard and exposure thresholds, not volume and category of use thresholds. Further, Option 3 reduces the level of pre-market assessment (based on indicative risk); retains the capacity to undertake risk assessment for potentially medium and high risk chemicals (Class 3); and has the capacity to impose conditions of use where this is necessary, without usurping the role of existing risk management agencies.

Options 2 to 4 would all streamline NICNAS's risk assessment processes and re-focus NICNAS's efforts on high risk chemicals.

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, therefore, it is 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 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. Individual chemicals (including in fluids) that are intentionally released or leach from articles would be regulated by NICNAS. For clarity, specific exclusions for articles may be prescribed in the Regulations.

- *Chemicals in cosmetics* - It is proposed that the ACCC take 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.

- *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 the Environment once it had the ability to capacity to assume the responsibility.

- Under the Stockholm Convention, NICNAS currently has no import or export related responsibilities. Rather, NICNAS takes into account nationally adopted criteria, such as for persistence, bioaccumulation and toxicity, when undertaking assessments of new and existing chemicals. It is proposed that NICNAS would continue to do this under any each 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 for those agencies to fulfil their 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 the overall risk management framework and NICNAS's relationship with risk management agencies. Issues and views 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.

Cosmetics and Cosmetic Ingredient Regulation

As stated previously in this RIS, the primary objective of this reform is to retain NICNAS's role to assess the human health and environmental risks

of industrial chemicals, while refocusing its efforts on high risk chemicals. Options 2-4 all achieve this objective to differing degrees.

Options 2-4 all recommend the transfer of the existing Cosmetic Standard from NICNAS to the ACCC.

Each of possible reform Options 2-3 deliver significant benefit and streamlining associated with the introduction of chemicals to be used in cosmetics (i.e. cosmetic ingredients). In 2012-13, ~75% of the 7,300 new chemicals notified to NICNAS were introduced under cosmetic specific exemptions from assessment. Under the current preferred option, the number cosmetic chemicals likely to be assessed pre-market by NICNAS is expected to be further reduced to ~0.1% of total cosmetic introductions (i.e. a ~90% reduction in the number NICNAS assesses pre-market), with the majority being introduced under Class 2 (industry self-assessment and notification).

The need for further reform to the regulation of cosmetics will be a decision of Government, and may be considered once the residual regulatory burden of cosmetics and cosmetic ingredients based on the implementation of the current NICNAS reform is evidenced and evaluated.

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 10 percent of total Australian manufacturing activity[24]. 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. In 2012-2013, there were 5,290 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 of the scheme fully recovered through industry fees and charges for assessments and registrations. The annual operating budget is approximately $10 million.

[24] Department of Industry. (http://www.innovation.gov.au/industry/chemicalsandplastics/Pages/default.aspx)

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 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 environment[25];
- 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.

[25] The Council of Australian Governments agreed to develop a national approach to environmental management of chemicals, which is being progressed, by Environment and Ministers, in parallel with the review of NICNAS.

Option 1: Base case – make no changes to the scope or activities of NICNAS.

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 uncertainty 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 uncertainty 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 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's 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 grand-parented 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 businesses, 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) can result in unnecessary costs to businesses 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's 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 5 - Elapsed time to prepare for, notify and then receive assessment of notifications and permits compared with statutory timeframes[26]

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

*The ICNA Act enables the Minister to extend this period by up to 90 days, if it is not reasonably practical for the assessment to be carried out thoroughly and report completed within this period.

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*

  Industry has reported that reformulation costs are associated with changing a chemical product's ingredients in response to (or in anticipation of) NICNAS's 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.

[26] Source: Identified by industry stakeholders interviews, undertaken by KPMG in 2012.

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.

The extent of these impacts depends on the level of contact a 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's 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's ability to protect public health and the environment (through timely assessment of higher risk chemicals).

NICNAS's current regulatory tools are inadequate to effectively undertake its expected role. Specifically, NICNAS's limited powers to gather and request information together with restricted compliance and enforcement tools result in inefficiencies that hinder NICNAS's ability to adequately fulfil 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 2012-13, NICNAS issued 119 permits, all containing conditions of use;

- in 2012-13, NICNAS issued 162 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 conditions of use, including chemicals for which regulatory responsibility has been transferred from TGA to NICNAS.

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: Focus on post-market regulatory controls for both new and existing industrial chemicals with the assessments requirements informed by category of use and volume.

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), including 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.

Approximately ~65% of chemicals requiring pre-assessment by NICNAS under status quo (Option 1) would be introduced under Classes 1 or 2 (25% and 40% respectively) under Option 2.[27] Those chemicals assessed prior to market by NICNAS would represent ~1% of the approximate 9,000 introductions in a year.

[27] By applying the indicative criteria outlined in the description of Option 2 to those chemical assessments, both permits and certificates, undertaken during a two year period 2010/11-2011/12

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 assessed or inadequately mitigated risks to avoid harms during the time between the chemical's introduction and the identification and remediation by NICNAS and risk managers through post-market activities.

A similar style of regulatory system in New Zealand is reported to have a very high non-compliance rate, with public concerns that significant harm to the people and environment of New Zealand may be occurring and that the current system has increased the potential for catastrophic, acute and chronic harm. The costs to the community from a failure to manage risks to public health or the environment may be significant (e.g. $25.8 million for the remediation of extreme environmental damage[28]).

There is also a risk that unscrupulous operators may seek to capitalise on the delay between introduction and NICNAS compliance checks (not all introductions would be able to be audited) by introducing unsafe products for short term gains. Again, the difficulty attributing any adverse effects to a particular chemical should not be understated.

On the other hand, the reduction in unnecessary regulatory costs for new chemicals has the potential to lead to improvements in public health, worker safety 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 assessment costs are reduced). However, the market reality may be that it is more profitable to make a product using older, cheaper but more toxic ingredients, than it is to make a competitively priced alternative that achieves the same results with newer, nontoxic, biodegradable ingredients. Safer alternatives may not be competitively priced in the market, creating disincentives for companies wishing to make R&D investments in 'green chemistry'. Currently, global market pressures arise from less developed (and less regulated) countries where cheap old technologies still dominate manufacturing.

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. Furthermore, the

[28] National Environment Protection Council Service Corporation (NEPCSC) - *Consultation Regulatory Impact Statement – Management of chemical environmental risks* – April 2013 - http://www.scew.gov.au/consultation/management-chemical-environmental-risks-consultation-regulation-impact-statement

range and type of chemicals introduced might not necessarily be safer chemicals, especially if sourced from a country with a less stringent chemical safety regulatory system. Many countries are also paying more attention to the safety of chemicals that will be used domestically, and are less concerned about chemicals that are only used for export.

In addition, the reliance on self-assessment for new chemicals will decrease the level of information NICNAS possesses (and publishes) on the use and introduction of chemicals. Environmental and community stakeholders are already concerned about the lack of information available on chemicals in use in Australia. The identification of chemicals that may be responsible for an observed adverse effect may become more difficult to establish through current health and environmental surveillance processes.

The capacity for industry to introduce any chemical that has been approved by another recognised country would continue to concern health and environmental stakeholders. Greater use of international assessment materials without regard to there being different environmental or industrial conditions in Australia may cause more damage than would occur in another country. The environmental uniqueness of Australia is due to two key reasons: Australia has relatively less sophisticated environmental disposal infrastructures (e.g. few high temperature incinerators) than some first world countries; and Australia has a distinct environment, in relation to unique flora and fauna and an inherently dry landscape. Exposure calculations for the environment are location specific and consider variables such as, for example, population in a region, volumes of water discharged to sewers and sewage treatment plant design. The presence of intermittent creek and river flows, due to extreme rainfall and temperature fluctuations compared to Europe and North America also means that chemicals are likely to be present in the aquatic environment at higher concentrations than similar release scenarios internationally.

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 (that may have been detected in a pre-market assessment) after the chemical has been brought to market.

Under this option a large volume of a cosmetic chemical (up to 10,000kg) may be introduced without any notification to NICNAS provided the introducer self-assesses the chemical to be of no unreasonable risk. These chemicals are intentionally placed directly on the skin and therefore the public exposure is high and repeated. Furthermore, there is concern that many of these chemicals, particularly fragrances, may be sensitisers. The methods for determining if a chemical is a sensitiser and calculating a safe concentration is technically challenging. Thus there is concern that under this option an increase in the incidence of allergic reactions and other health effects from cosmetic chemicals may be seen. Post-market, this would only be known through consumer adverse health outcome reporting from use of a product. To then assign causality to a particular ingredient is extremely difficult, due to scientific limitations in assessing effects of low doses of individual (or synergistic) chemicals in mixtures, given the presence of many confounding factors, such as lifestyle and exposure to many other chemicals.

From an environmental fate and exposure perspective, cosmetics can behave quite differently to other industrial chemicals. Across the country, almost the entire volume of cosmetics is released to sewers. Treated waste waters and biosolids released from sewage treatment facilities often still contain significant levels of residual cosmetic chemicals. This can lead to long-term aquatic exposure. The consequences of this exposure can be difficult to predict but can include adverse environmental and public health outcomes. Exposure considerations for cosmetics are often more complex than other chemicals and assessment of these chemicals can be challenging for some chemical notifiers.

Industry

Businesses looking to introduce a new chemical would need to determine which class applies to the chemical and its intended use. The obligations on businesses would reflect the risk posed by the chemical. For example:

Class 1	Businesses introducing these chemicals in the defined situations would be exempt from pre- and post-market obligations under the ICNA Act. Businesses would be required to comply with any existing state or territory legislation, for example, workplace health and safety public health and environmental regulations.
Class 2	Businesses would be required to collect the necessary data to support a self-assessment against legislative criteria and provide notification to NICNAS at the time of introduction of the chemical. Businesses would be required to provide annual confirmation of these chemicals.

Class 3	Businesses would be required to collect the necessary data to substantiate an application and develop the necessary paperwork for a pre-market assessment by NICNAS. Businesses would be required to address any follow-up questions from NICNAS in relation to the application. The chemical could only be introduced following issuance of a certificate by NICNAS.

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

- reduce costs to industry[29]. 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 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 however there is no data to support this assertion;

- reduce the time taken to get new products to market; and

- improve opportunities for planning 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 some increase in costs associated with corresponding safeguards being applied (e.g. monitoring and annual reporting obligations). Further:

- it is feasible that other government departments may expand their roles, or businesses themselves will perform risk management

[29] 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.

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's mandatory information-gathering powers are extended to the degree necessary to undertake effective post-market surveillance (with attribution of effects to particular chemicals). The extent of this impact would depend on the frequency of NICNAS's level of auditing and information requests to industry.

If under Option 2, industry fails to manage risks appropriately for new chemicals introduced in under class 1 and 2, the costs to industry arising through regulatory action by risk managers may be significant. Further, 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.

Option 2 would be expected to deliver a reduction in the annual compliance cost for industry when compared with Option 1. Reforms to the level of pre-market assessment required for the majority of chemicals would be expected to reduce the burden (cost of effort) industry commits to the preparation of new chemicals assessment packages and reduce industry's external consultant costs.

Self-assessment of more complex or higher risk chemicals (yet not requiring pre-market assessment by NICNAS) would however be expected to place some additional demand on consultancy costs as well as increase industry training costs.

While a more streamlined annual reporting mechanism will be introduced, with a greater number of chemicals introduced following self-assessment (rather than pre-market assessment by NICNAS), industry as a whole would be expected to see an increase in annual reporting costs.

Under option 2, the reduction in barriers to market for a greater of number chemicals, those in Class 1 and 2 which have minimal notification obligations, would be expected to significantly decrease the cost to business associated with delays to market. Additionally, streamlining of pre-market assessment processes, including better utilisation of international assessment materials, would also be expected to reduce time to market for class 3 chemicals.

Table 6 provides an estimate of the cost off set to industry from Option 2.

Table 6 Regulatory Burden and Cost Offset (RBCO) Estimate Table for Option 2

Average Annual Compliance Costs (from Business as usual)				
Costs ($m)	**Business**	**Community Organisations**	**Individuals**	**Total Cost**
Cost of Effort	-2.602.60	0.0	0.0	-2.602.60
Consultant Costs	-1.531.53	0.0	0.0	-1.531.53
Staff Training	+010.01	0.0	0.0	+0.0101
Annual Reporting	-25.64	0.0	0.0	-25.64
Delay to Market Costs	-0.63			-0.63
Total of Costs (by sector)	--30.4	0.0	0.0	-30.4
Cost offsets ($m)	**Business**	**Community Organisations**	**Individuals**	**Total by source**
Agency	0.0	0.0	0.0	0.0
Within portfolio	0.0	0.0	0.0	0.0
Outside portfolio	0.0	0.0	0.0	0.0
Total by Sector	**0.0**	**0.0**	**0.0**	**0.0**
Proposal is cost neutral?	□ yes	X no		
Proposal is deregulatory	X yes	□ no		
Balance of cost offsets	-$30.4			

This option is not expected to increase the overall resources drawn through cost recovery from industry; rather it will change the nature of how these resources are collected. With a reduction in pre-market assessments and a move to industry self-assessment with post-market monitoring or auditing (i.e. Class 1 or 2), a revision of the existing cost recovery arrangements will be necessary to ensure that NICNAS can deliver the post market monitoring and auditing framework necessary to safeguard the protection of public health, worker safety and the environment. The Australian Government Cost Recovery Guidelines (July 2014) require a Cost Recovery Impact Statement (CRIS) be developed as part of the implementation arrangements for this option. This process will review the fee structure to ensure that NICNAS can continue to operate effectively on a full cost recovery basis, while taking into account the existing and predicted burden on industry, including the nature of fees for the remaining streamlined assessments and the extent of any increase in the existing levy on industry (if required).

NICNAS

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.

A preliminary estimate by the Department of Health is that initial implementation of this option to establish the new arrangements may require $12.5 m over two years. A component of this funding would include development and implementation of new IT systems, development of new guidance material resources for stakeholders and implementation of new procedures to support the reforms. Further analysis would be required to establish the justification for any such increase in resources.

Once the reforms are implemented, the ongoing operation of NICNAS 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 focuses on post-market monitoring and enforcement, there will be greater regulatory effort directed to chemicals already on the market.

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

Option 3: Pre- and post-market regulatory controls for new chemicals, post-market regulatory controls for existing chemicals, with the assessment requirements informed by hazard and exposure.

In summary, this option involves NICNAS adopting an 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 three classes of industrial chemicals, each with different pre and post-market requirements.

Approximately 77% of chemicals requiring pre-assessment by NICNAS under status quo (Option 1) would be introduced under Class 1 or Class 2 (3% and 74% respectively) under Option 3.[30] NICNAS pre-market assessments would impact 0.75% of the total introductions in a year. Therefore, like Option 2, Option 3 would see a reduction in the number of chemicals requiring assessment by NICNAS prior to market compared with the status quo (Option 1)

Community

In relation to chemicals falling within Classes 1 and 2 (no NICNAS 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

[30] By applying the indicative criteria and risk matrix outlined in the description of Option 3 to those chemical assessments, both permits and certificates, undertaken during a two year period 2010-12

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 or 2 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 and 2 (i.e. those chemicals not requiring pre-market assessment).

In relation to Class 3, chemicals that would continue to require pre-market assessment by NICNAS:

- this option assures consumers that chemicals anticipated to have medium and higher potential risk will continue to be subject to pre-market assessment by NICNAS. This is, therefore, likely to provide a greater level of public confidence and greater transparency through the availability of assessment information for medium and higher risk chemicals than Option 2;

- providing NICNAS with the ability to impose conditions of use 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 gap and uncertainties 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 (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.

Like Option 2, businesses looking to introduce a new chemical would need to determine which class applies to the chemical and intended use. The obligations on businesses would reflect the risk posed by the chemical (see examples described in Option2)

In relation to chemicals falling within Classes 1 and 2 (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 potential 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 1 and 2) would be expected to reduce permit and certificate assessments by a minimum of 77 per cent[31].

- 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 current relevant assessment timeframes.

- 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 reduce 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 regulatory effort is likely to lead to the introduction of a greater number of new chemicals including safer, modern and cost-

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

effective chemical substitutes, increased competition and increased chemical innovation.

- Greater alignment with international regulatory arrangements (for Classes 1 and 2) 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 Australian industries competing with imported products. Greater alignment between such aspects of chemical notification as data requirements, automatic entry class and volumes in Australia and internationally may also assist in simplifying the notification processes.

- 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.

While these impacts represent a significant improvement on Option 1 (base case) these benefits to industry are not likely to be as significant as for Option 2 where more chemicals would be eligible for automatic entry or notification only.

In relation to Class 3 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 determined to be potentially of lower risk (i.e. lower for Class 3 Medium-High Risk Chemicals) will have shorter assessment periods. This is estimated to be at least 35% of all permit and certificate assessments.[32]

- Allowing NICNAS, in consultation with other risk management agencies, to include conditions of use 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 conditions of use). These circumstances could be expected to occur in limited situations with

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

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 regulatory burden on industry.

In relation to existing chemicals:

- Expanding NICNAS's functions to include particulars and conditions of 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 secondary notification. Therefore, it 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.

- 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's 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's 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.

Like Option 2, 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. However, as this option limits the type of chemicals introduced without notification to those less likely to pose a significant risk to public health or the environment (i.e the criteria for Class 1 is more restrictive), it anticipated that with NICNAS possessing information on a greater percentage of chemicals introduced, risk managers are less likely to adjust existing regulatory approaches.

Expanding NICNAS's risk management functions to include the monitoring and enforcement of conditions of 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 2-4), there is likely be an initial increase in costs to industry as the result of industry stakeholders needing to familiarise themselves with the new requirements. This impact is likely to be felt more strongly by smaller businesses.

Option 3 would be expected to deliver a significant reduction in the annual compliance cost for industry when compared with the Option 1 and a slight reduction compared with Option 2.

Similar to Option 2, reforms to the level of pre-market assessment required for the majority of chemicals would be expected to reduce the burden (cost of effort) industry commits to the preparation of new chemicals assessment packages and reduce industry's external consultant costs.

The reduced burden associated with introducing a chemical class 1 or 2 (compared with pre-market assessment) would be expected to outweigh

any additional resourcing industry commits to the determination of classes using the risk matrix.

Like Option2, the reduction in barriers to market for a greater of number chemicals would also be expected to significantly decrease the cost to industry. With a greater number of chemicals in class 3 (compared with Option 2), streamlining of pre-market assessment processes in option3 would be expected to reduce time to market.

Table 7 provides an estimate of the cost off set to industry from Option 3.

Table 7: Regulatory Burden and Cost Offset (RBCO) Estimate Table for Option 3

Average Annual Compliance Costs (from Business as usual)				
Costs ($m)	**Business**	**Community Organisations**	**Individuals**	**Total Cost**
Cost of Effort	0.9	0.0	0.0	0.9
Consultant Costs	2.1	0.0	0.0	2.1
Annual Reporting	-24.0	0.0	0.0	-25.0
Delay to Market Costs	-0.7			-0.7
Total of Costs (by sector)	-21.7	0.0	0.0	-22.7
Cost offsets ($m)	**Business**	**Community Organisations**	**Individuals**	**Total by source**
Agency	0.0	0.0	0.0	0.0
Within portfolio	0.0	0.0	0.0	0.0
Outside portfolio	0.0	0.0	0.0	0.0
Total by Sector	0.0	0.0	0.0	0.0
Proposal is cost neutral?	□ yes	X no		
Proposal is deregulatory	X yes	□ no		
Balance of cost offsets	-$22.7			

Like Option 2, this option is not expected to increase the overall resources drawn through cost recovery from industry; rather, it will change the nature of how these resources are collected and used. With a reduction in pre-market assessments and move to industry self-assessment with post-market monitoring or auditing (i.e. Class 1 or 2), a revision of the existing cost recovery arrangements will be necessary to ensure that NICNAS can deliver the necessary post-market monitoring and auditing framework. This revision process would determine the nature of fees for the remaining streamlined assessments and the extent of any increase in the existing levy on industry to fund the increased post-market surveillance. As with Option 2, the Australian Government Cost Recovery Guidelines

(July 2014) require that a CRIS be developed as part of the implementation arrangements for this option.

NICNAS

A preliminary estimate by the Department of Health is that initial implementation of this option to establish the new arrangements may require $12.5 m over two years. A component of this funding would include developing and implementing new IT systems, development of new guidance material resources for stakeholders and implementation of new procedures to support the reforms. 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's organisational structure and on the focus of its staff.

- Expanding and strengthening NICNAS's regulatory tools will likely result in stronger and improved decision-making. Greater information gathering powers and compliance tools will enable decisions made by NICNAS to be better informed and validated.

- A graduated and effective mix of compliance provisions will strengthen NICNAS's 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.

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 conditions of 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: Continued focus on pre-market regulatory controls for new chemicals and post-market regulatory controls of existing chemicals, with the assessment requirements informed by category of use and volume

In summary, this option significantly reduces the number of chemicals exempt from regulation or subject only to notification to NICNAS compared to Options 2 and 3, with the default position being assessment by NICNAS. Efficiency is gained through reducing NICNAS's risk assessment processes following notification. With the increase in pre-market activity, there would be expected to be some reduction in post-market monitoring and enforcement activity/ However, it is expected that there would be a net increase in costs incurred by NICNAS and, therefore, subject to cost recovery from industry.

Whilst not to the same extent as the other options, Option 4 will reduce the number of chemicals requiring pre-market assessment by NICNAS. Approximately 36% of chemicals requiring pre-assessment by NICNAS under status quo (Option 1) would be introduced under Class 1 or Class 2 (11% and 25% respectively) under Option 4. NICNAS pre-market assessments would represent approximately 2% of the (approximately 9,000) new chemicals introduced each year.

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 identified or inadequately mitigated risks arising from self-assessment of new chemicals or the automatic introduction into Australia of certain chemicals approved by other comparable countries. It is likely that relative to other options this would minimise 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

Under Option 4, businesses would be required to: collect the necessary data to substantiate an application; develop the necessary paperwork for a pre-market assessment by NICNAS; and address any follow-up questions from NICNAS in relation to the application. Businesses would be able to introduce the chemical only following issuance of a certificate by NICNAS.

Like Option 2, businesses looking to introduce a new chemical would need to determine which class applies to the chemical and intended use. The obligations on businesses would reflect the risk posed by the chemical (see examples described in Option2)

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 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 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 4 would result in increased regulatory requirements on businesses prior to the introduction of a chemical, there would be some corresponding decrease in NICNAS post-market monitoring. This would not be expected to entirely offset the increased pre-market requirements.

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

Option 4 would be expected to deliver a significant reduction in the annual compliance cost for industry although less than expected for Options 2 or 3.

Streamlining of pre-market assessment processes would be expected to reduce the time to market delays as well as reduce the level of effort (including external consultant costs) for industry. The focus on pre-market assessment would not be expected to lead to an increase in annual reporting costs or staff training.

Table 8 provides an estimate of the cost off set to industry from Option 4.

Table 8: Regulatory Burden and Cost Offset (RBCO) Estimate Table for Option 4

Average Annual Compliance Costs (from Business as usual)				
Costs ($m)	**Business**	**Community Organisations**	**Individuals**	**Total Cost**
Cost of Effort	21.8	0.0	0.0	21.8
Consultant Costs	14.8	0.0	0.0	14.8
Annual Reporting	-25.7	0.0	0.0	-25.7
Delay to Market Costs	-0.5	0.0	0.0	-0.5
Total of Costs (by sector)	10.4	0.0	0.0	10.4
Cost offsets ($m)	**Business**	**Community Organisations**	**Individuals**	**Total by source**
Agency	0.0	+/-0.0	+/-0.0	0.0
Within portfolio	0.0	0.0	0.0	0.0
Outside portfolio	0.0	0.0	0.0	0.0
Total by Sector	0.0	0.0	0.0	0.0
Proposal is cost neutral?	□ yes	X no		
Proposal is deregulatory	X yes	□ no		
Balance of cost offsets	-$10.4			

This option is likely to require an increase in the overall resources drawn from industry associated with the increase in pre-market assessments. A revision of the existing cost recovery arrangements will be necessary to determine the nature of fees for components of the new and streamlined pre-market assessment process, while maintaining sufficient post-market surveillance to promote regulatory compliance. Option 4 also requires the Australian Government Cost Recovery Guidelines (July 2014) require that a CRIS be developed as part of the implementation arrangements for this option.

NICNAS

This option is likely to require greater ongoing resources for NICNAS to process an increased number of pre-market applications (noting that these costs would need to be recovered from industry under current cost recovery rules). A preliminary estimate by the Department of Health is that initial implementation of this option to establish the new arrangements may require $12.5 m over two years. A component of this funding would include developing and implementing new IT systems, development of new guidance material resources for stakeholders and implementation of new procedures to support the reforms. 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 (then) Department of Health and Ageing and the (then) Department of Finance and Deregulation in June 2012.

Following the June 2012 workshops, there have 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 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.

Further information sessions were held in association with the release of a revised draft RIS in June 2013 and provided additional opportunity for stakeholders to provide comments and feedback on the detail of options for reform.

Further consultations with key industry association and community group stakeholders were held in Canberra on 6 and 20 August 2013, respectively. These meetings provided stakeholders with the opportunity to express their views on options for reforming NICNAS in the revised RIS.

Targeted stakeholder consultation on the proposed options for NICNAS reform, with the draft RIS circulated for targeted consultation on 17 July 2014, with a request for written submission by 8 August 2014. In addition, face-to-face consultations with key industry associations and consumer, community, environment and professional groups and associations were held on 24 and 25 July 2014. These meetings provided

stakeholders with the opportunity to provide comment on the revised options for reforming NICNAS in the RIS.

Outcome of consultations to date

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;
- NICNAS focusing on risk assessment rather than risk management, specifically that NICNAS should not be able to impose conditions of 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;
- some strengthening of compliance and enforcement provisions in accordance with the level of risk;
- improving the mechanism for the assessment of priority existing chemicals; and
- controlled exchanged of commercial business information between NICNAS and risk managers provided adequate safeguards are in place.

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

- expressed concern over the absence of notification or record requirements for lower risk chemicals;
- expressed concern that NICNAS's 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;
- highlighted current uncertainties and '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;

- supported the amendments to give NICNAS the power to impose conditions, restrict or ban chemicals; and

- considered an adverse event reporting system an essential component of any regulatory framework.

These views have informed the options presented in this RIS.

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

- the complex assessment processes;

- the definition of "new chemical";

- 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 need to better utilise hazard assessments undertaken in other national regulatory functions as well as international regulatory frameworks;

- the lack of international harmonisation, particularly for cosmetic ingredients and products;

- the lack of flexibility for NICNAS to deal with chemicals introduced in low concentrations, such as fuel additives;

- the limited ability of NICNAS to undertake urgent assessments or re-assessments in response to issues of immediate concern;

- the need to consider human health, worker safety and environment when assessing new chemicals;

- secondary notification of chemicals;

- the need to increase utilisation of information technology to achieve further efficiency gains; and

- limiting the scope of industrial chemicals regulation to only hazardous chemicals.

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 2-4. 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 4). Regardless of how many assessments are undertaken by NICNAS, it is broadly recognised that there is a need to streamline the assessment process.

In terms of NICNAS's assessment of existing industrial chemicals, many stakeholders expressed concern about the slow progress NICNAS has made in assessing the approximately 38,000 existing chemicals on AICS that remain unassessed.

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 existing 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 (nor any practical method to remove from AICS chemicals no longer 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's inability to undertake comprehensive post-market monitoring and enforcement of compliance. Some specific areas of concern included:

- NICNAS's inability to track, use and gather data (resulting in a limited understanding of the longer term effects of chemicals in Australia);

- NICNAS's 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 2-4.

Industry stakeholders principally favoured Option 2 as the most likely to bring efficiency gains to industry and promote the introduction of new chemicals. Industry, whilst supportive of the alignment of risk to regulatory action in Option 3, expressed concern that some of the thresholds and criteria for the classes were too restrictive to permit significant efficiency gains. Additionally, industry stakeholders did not see a need for NICNAS to have the ability to apply conditions of chemicals given the operations of existing risk managers. Industry considered Option 4 excessive and likely to lead to significant barriers to innovation.

Community stakeholders considered Option 3 as a pragmatic approach to the delivery of efficiency gains for industry whilst ensuring the protection of human health and the environment although they did consider some of the threshold, criteria, monitoring and auditing in the classes as inadequate. The ability of NICNAS to apply limitations and controls were viewed as an essential component of an effective framework. Some community stakeholders viewed Option 4 as their preferred approach, in that it would be most likely to lead to increased protection of human health and the environment.

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 4) 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.

Options 2 through 4 would be expected to address the three main problems identified with the existing regulatory framework to varying extents.

Taking into account the views of all stakeholders, Option 3 is the preferred option as it delivers the highest net benefits across all groups of stakeholders. Compared with the other options, Option 3 also achieves:

- a significant reduction in regulatory costs associated with the application of the regulatory framework. Whilst Option 2 would achieve a greater saving, Option 3 limits the type of chemicals introduced without notification (i.e. Class 1) to those less likely to pose a significant risk to public health or the environment, thereby reducing the risk of unintended harms (and associated recovery costs) as well as the likelihood that other risk managers will alter their regulatory approaches to address a perceived reduction in protection.
- a balance between pre-market and post-market controls, based on the anticipated risk posed by the chemical. A well designed, risk based 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; and
- a greater alignment with international regulatory arrangements (i.e. through the criteria for Classes 1-3), will allow increased utilisation of both international data and assessments to reduce the regulatory burden on the introduction of new 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.

Option 3 also allows NICNAS, in consultation with government risk management agencies, to include conditions of use 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 (Option 3), it is proposed that:

- further consultation be undertaken from May – August 2015 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);

- assuming government policy authority, the amending legislation be introduced into Parliament during early in the 2015 Spring sitting period;

- subject to Parliamentary passage of the necessary legislative changes in late 2015, the proposed changes may take effect commencing from 1 September 2016, with full implementation by 1 September 2018;

  during 2015/16, delegated legislation 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 Implementation Statement (CRIS). It is anticipated that, if the primary legislation is passed in late 2015, consultation on the proposed fees and CRIS could occur by from early 2016 to enable the new fees arrangements to be reflected in delegated legislation;
- NICNAS to make changes to systems to reflect the new processes, including development of IT systems;

- NICNAS to update guidance materials to reflect the changes;

- industry to become acquainted with new requirements; and

- broadly based stakeholder education to occur.

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 2012-13, approximately 700[33] new companies wishing to import and/or manufacture industrial chemicals for commercial purposes registered with NICNAS for the first time with a further 4,600[34] 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.

Combined, the activities above accounted for 266 of NICNAS's 287 notification and assessment applications in 2010-11[35].

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[33] NICNAS, NICNAS Annual Report 2012-13, Canberra 2013. Online reference: (http://www.nicnas.gov.au/__data/assets/pdf_file/0017/8252/NICNAS_Annual_Report_2012-13.pdf)

[34] Ibid

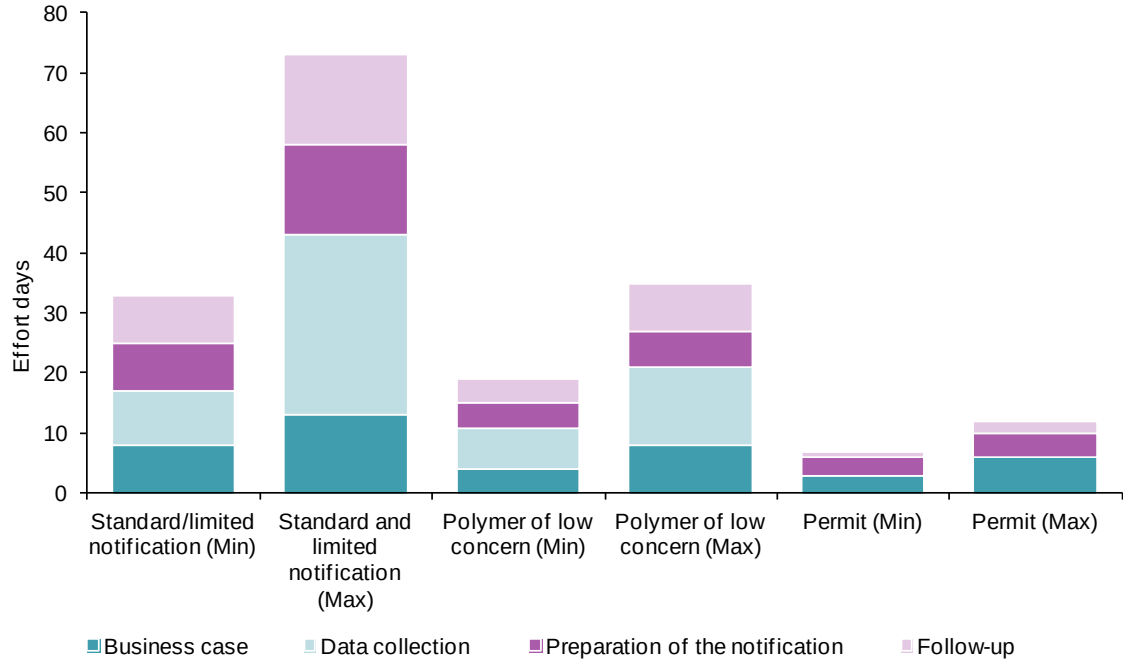
[35] unpublished data provided by NICNAS

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 diagram (Diagram A1), 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.

Diagram A1: 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)[36]

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[37] Max: $16,800[38]	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's 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.

[36] Source: Identified by industry stakeholders during interviews undertaken by KPMG in 2012.

[37] Limited notification assessment fee.

[38] Standard notification assessment fee

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

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 permits[39]

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 ICNA Act enables the Minister to extend this period by up to 90 days, if it is not reasonably practical for the assessment to be carried out thoroughly and report completed within this period.

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 Standard, Limited and PLC categories. The statutory timeframe for an EIP

[39] Source: Identified by industry stakeholders in interviews undertaken by KPMG in 2012.

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.

Reformulation costs

Industry has reported that in anticipation of, or in response to, NICNAS's 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.[40]

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 forgone 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).

[40] 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 that 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's 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 reports[41]

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

[41] Source: Identified by industry stakeholders in interviews undertaken by KPMG in 2012.

Attachment B – Summary of international approaches to the regulation of industrial chemicals

The following table provides a summary of the regulatory approaches to industrial chemicals in Australia, New Zealand (NZ), the United States of America (USA), Canada and the European Union (EU).

Key features	Australia	NZ	USA	Canada	EU
Main Regulatory Authority	NICNAS	Environmental Protection Agency	Environmental Protection Agency	Environment Canada (and Health Canada)	European Commission – European Chemicals Agency
Legislation	ICNA Industrial Chemicals Notification and Assessment Act (1989)	HSNO Hazardous Substances and New Organisms Act (2006)	TSCA Toxic Substances Control Act (1976)	Canadian Environmental Protection Act (1999)	REACH Registration, Evaluation, Authorisation, Restriction of Chemicals (2007)
Regulated entities	Manufacturers and importers	Manufacturers and importers	Manufacturers and importers	Manufacturers and importers and downstream users (if not a different use from that assessed)	Manufacturers and importers and downstream users
Emphasis	Pre-market notification and assessment of new chemicals	Industry self-assessment. EPA function focussed on risk management and compliance	Pre-market notification and assessment of new chemicals	Pre-market notification and assessment of new chemicals	Industry self-assessment but ECHA reviews submissions for chemicals of concern
Key features of new chemical Regulation					
New Chemical defined as	Chemical not listed on AICS or use is not within the conditions of use defined by AICS annotation	Substance not listed on the NZ Inventory of Chemicals. Includes agricultural chemicals and veterinary medicines	Chemical not listed on TSCA Inventory	Chemical not listed on the Domestic Substances List	Chemical not registered (or pre-registered under REACH

Key features of new chemical Regulation					
Scope of risk assessment	Public health, worker safety and environment	Public health, worker safety and environment	Public health, worker safety and environment	Public health and environment	Public health, worker safety and environment
Exclusions from Regulation	Microorganisms	Non-hazardous substances	Cosmetics	n/a	Substances known to be non-hazardous such as water, air and nitrogen
Pre-market assessment for new chemicals	Regulatory agency assessment of new chemicals	Only for some chemicals (hazardous)	Regulatory agency assessment of new chemicals	Regulatory agency assessment of new chemicals	Registration with REACH (by introducer)
Abbreviated assessments for new chemicals (not added to inventory)	Through exemptions and permits	n/a	Through exemptions	Through special categories	n/a
Impose mandatory control measures/ban	Recommendations only, cannot ban	Yes – restriction and rejection	Yes – EPA can limit or prohibit use	Yes – restriction or prohibition	Yes – restriction, authorisation,
Key features of existing chemicals regulation					
Priority of assessments	ICNA Act allows the Minister to decide that a 'Priority Existing Chemical' must be assessed, and that industry must provide information to NICNAS. An accelerated non-statutory scheme for assessing existing	All existing substances (single chemicals and mixtures) classified. No prioritisation activities planned.	Assessment of priority chemicals based on criteria rather than screening/ prioritizing entire TSCA Inventory of ~84,000 chemicals. Prioritisation for chemicals of concern to children's health, used in children's	Categorisation and prioritisation of whole DSL, based on PBT and toxic chemicals with high exposure potential	All chemicals introduced at >1 tonne/year must be registered by stipulated registration deadlines. Prioritisation occurs based on CMR, PBT and high volume.

Key features of existing chemicals regulation					
	chemicals (IMAP) does not require industry to provide data, and considers chemicals: with exposure information, found in cord blood; of concern and subject to regulatory action overseas		products, neurotoxic, PBT, carcinogen, detected in biomonitoring		
Inventory states chemical uses	No	Yes	Yes	Yes	Registration dossiers identify uses
Outcomes assessment	Recommendations Annotation of ACIS	Hazard controls on all substances	Controls, restrictions, bans	Risk management measures, Virtual elimination	Registration, Authorisation, Restriction
Impose mandatory control measures	NICNAS recommends risk controls	Risk controls prescribed by Group Standards or EPA	Risk control measures prescribed in consent order	Risk management measures and virtual elimination	Risk controls recommender by ECHA or imposed through authorisation/restriction
Powers to ban chemical	No	Yes – withdraw approval	Yes – EPA can limit or prohibit use	Yes – virtual elimination	Yes – after transition period to allow member states to take action
Assessment report	Full report public	Yes	Full public report	Yes	Yes, registration dossier published (unchecked)
Reassessment	Secondary notification (for new use, data etc)	Reassessment may be initiated by introducer or EPA	TSCA Section 8(e) notice for increased risk	SNAc (for new use, data etc)	Registration updated may be initiated by Registrant or ECHA7

Attachment C – Summary of international industrial chemical regulation fees and assessment arrangements

SOURCE: NICNAS (Updated 24/04/14)
http://www.nicnas.gov.au/about-nicnas/cost-recovery/cris-2012-2016-full-version/appendix-b-benchmarking-indicators-of-agency-costs

European Chemicals Agency (ECHA)

ECHA has received pre-registrations for over 140,000 substances from 65,000 companies. By 1 December 2010, ECHA had received approximately 25,000 registrations covering almost 4,300 distinct substances, of which close to 3,400 were phase-in substances covered by the deadline. Additional registrations were received after the deadline, bringing the overall number of registrations submitted in 2010 to just over 25,600.

Standard fees for the registration of a single substance under REACH range from €1,600 to €31,000 (2008 fees in European Commission Regulation 340/2008). Fee reductions are available for joint submissions (€1,200 to €23,250). Special account has been taken of the potential impact of this regulation on medium-, small- and micro-sized enterprises (SMEs) and the need to avoid any discrimination against them. Fee reductions based on the size of the company range from 90 per cent for micro enterprises (<10 full time staff and <€2 million annual revenue) to 30 per cent for medium enterprise (<250 staff and €50 million annual revenue). Likewise a fee need not be paid for a registration of a substance in a quantity of between one and ten tonnes. The tonnage level is the only trigger.

The registration fees were estimated to raise €39 million in 2010 and €96 million for 2011. No European Union contribution is planned for the years 2011-2013; that is, it is anticipated that ECHA will fully cover its expenditure from fees and charges levied in accordance with the Fee Regulation during this period. In addition, ECHA will have to repay the EU subsidy received in 2010 (€35 million) to the Commission, based on the result of its budgetary outturn account for 2010.

The standard fee for authorisation is made up of a €50,000 base fee and a €10,000 fee for each additional substance and/or use and applicant (European Commission Regulation 340/2008). Each specific use of a substance needs to be authorised and hence if a substance is used in several different applications then the company/ies are required to pay additional fees. Several companies can jointly apply for authorisation and pay one full fee plus additional fee(s) for the number of co-applicants. As with registration fees, small business fee reductions apply.

The fees for authorisation are not paid until the time when the application is sent to ECHA. The decision on an Authorisation List from the Candidate List of substances is, at August 2011, yet to be finalised as the Candidate List is still being compiled. Hence no substantial fee income from authorisation will be received before the end of 2012. The fees and charges collected from authorisation were budgeted to be €900,000 in 2011; however, this income is expected to be delayed.

As the application process for authorisation has not yet commenced, it is difficult to estimate the exact cost for the assessment required for each application. It should also be noted that the authorisation process contains a number of steps before the actual application and those should also be covered by the fees and charges, e.g. identification of a SVHC and inclusion in the candidate list.

The REACH regulation provides for specific cases in which an appeal can be submitted before the Board of Appeal, e.g. when a negative decision on a registration dossier is taken. Appeals of ECHA decisions attract fees from €2,200 to 6,600 (European Commission Regulation 340/2008). Reduced fees apply for SMEs. The fees and charges to be collected from appeals were budgeted to be €230,000 in 2010 and €130,000 in 2011 based on budget figures released on 22 June 2011.

ECHA is required to establish and manage a Classification and Labelling Inventory based on the notifications from industry and contains the list of harmonised classifications under the EU's regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation). All hazardous substances placed on the market on 1 December 2010 and all substances subject to REACH registration (independently of their hazardous properties or respective deadlines) had to be notified on 3 January 2011 at the latest. For substances already registered under REACH, no additional notification was required. ECHA received about 3.1 million notifications covering approximately 107,000 different substances. The number of notifications exceeded expectations by 50 per cent. The 2011 budget estimates the revenue from CLP fees and charges will be €80,000.

From 1 June 2009, fees and charges are adjusted annually based on the European Index of Consumer Prices. In November 2010, staff numbers within the agency were around 480. This is expected to increase to well over 500 during 2011.

Canadian Industrial Chemicals Scheme

The Canadian New Substances Program assessment periods range from five to 120 calendar days, depending on the type and volume of substance being manufactured or imported. New chemical fees range from C$50 to C$3,500 (2010-11) for the assessment of a single new

substance. The fee is dependent on the type of notification and the company's dollar value of annual sales. For example, a company with greater than C$40 million annual sales will pay a higher fee than a company with C$13-26 million annual sales.

The New Substances fees recover various costs ranging from 100 per cent recovery for some items (those services which only benefit industry such as masked name requests) to less than 100 per cent according to the amount of benefit accrued to industry versus the general public. The estimated total cost of the New Substances Program across Health Canada and Environment Canada was approximately C$3.7 million in 2008-09 of which C$513,500 was cost recovered from industry through notification fees (Source: 2008-09 Departmental Performance Report). The fee to be recovered from the implementation of the cost recovery regulations was initially set to correspond to 22 per cent of the total cost of administering the New Substances Notification Program in 1998. Actual cost recovery through industry fees, however, is closer to 14 per cent.

The fee for searching the confidential section of the inventory ranges from C$62.50 to C$250 (2010-11). Fees for masked name applications range from C$150 to C$600 (2010-11).

In Canada, existing chemicals are assessed by Environment Canada and Health Canada under CEPA. One of the initiatives under CEPA was the prioritisation and categorisation of approximately 23,000 substances on Canada's DSL, and this was required to be completed by 14 September 2006 (i.e. seven years). Risk assessment of prioritised chemicals was conducted under the Chemicals Management Plan (CMP). Under the CMP, an average of 300 existing chemicals was assessed per year. This included detailed risk assessments as well as rapid screening assessments for lower priority substances. The CMP provided funds from 2006-2011. The cost of the risk assessment component of CMP in 2008-09 was C$5.6 million (Note: this C$5.6 million is a top-up of existing funds used to assess existing substances). In 2008-09, draft or final assessment decisions were published on 251 existing substances or groups of substances including 88 high priority substances. The Canadian Government has renewed the CMP and committed to ongoing funding in the June 2011 budget.

US Industrial Chemicals regulatory program

The Environmental Protection Agency (EPA) administers the New Chemicals Program under section 5 of the TSCA, which requires that any person who proposes to manufacture or import a 'new chemical', i.e. a chemical not listed on the TSCA Chemical Substances Inventory, must provide a pre-manufacture notice (PMN) to the EPA at least 90 days prior to commencing manufacture or import of that chemical.

At the EPA the average assessment time is 64 hours per PMN, however, 70-80 per cent are 'dropped' after screening with only 20-30 per cent having a full assessment. The EPA has no requirement to publish an assessment report. If the EPA takes no action within the 90-day review period, the submitter is free to manufacture or import the substance, or to manufacture, import or process the substance for a new use.

Based on the 2009 Annual Performance Report, approximately 1,200 new chemicals were notified to the EPA in 2008 and 1,100 in 2009. In 2008, approximately 10 per cent of notifications required risk reduction activities and this number was approximately 12 per cent in 2009. The maximum assessment time is 90 calendar days and new chemical fees range from US$100 to US$2500 (2011-12).

The Fiscal Year 2012 budget for the New Chemicals program is US$14.3 million. PMN review and management is the major activity. PMN fees are authorised by TSCA and contain a cap on the amount the agency may charge for a PMN review. The EPA is authorised to collect up to US$1.8 million in PMN fees in FY 2012 under current law. Under TSCA, companies with annual sales of less than US$40 million have fees capped at US$100. The EPA does not charge a fee to search the confidential section of the inventory.

The TSCA Chemical Substances Inventory includes approximately 84,000 chemicals in commerce. There are approximately 2,900 High Production Volume (HPV) chemicals in commerce produced at over 1,000,000 lbs per year, and an additional approximately 3,300 chemicals produced at over 25,000 lbs per year. In FY 2012 the EPA will allocate US$15.6 million7 to assess chemicals, which will include developing hazard characterisations for 500 HPV chemicals and initiating detailed chemical risk assessments of priority chemicals.