



**Australian Government**  
**Department of Health and Ageing**  
**NICNAS**

**National Industrial Chemicals Notification and Assessment  
Scheme**

**DRAFT COST RECOVERY IMPACT STATEMENT**  
2012-13 to 2015-16

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**Glossary of Terms and Abbreviations**

ABC	Activity Based Costing
AICS	Australian Inventory of Chemical Substances – a list of chemical identity data maintained by NICNAS; a legal device that distinguishes new from existing chemicals and lists all industrial chemicals in use in Australia between 1 January 1977 and 28 February 1990; includes new chemicals assessed since February 1990 and corrections as required.
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARTG	Australian Register of Therapeutic Goods
<i>CAC Act</i>	<i>Commonwealth Authorities and Companies Act 1997</i>
CEC	Commercial Evaluation Category permit
CEF	Community Engagement Forum (NICNAS) – NICNAS’s advisory group that identifies community concerns about the impact of industrial chemicals on the environment, public health and/or worker health and safety
CER	Commercial Evaluation category permit Renewal
COAG	Council of Australian Governments
Cost Recovery Guidelines	Australian Government Cost Recovery Guidelines (July 2005)
CPI	Consumer Price Index
CRIS	Cost Recovery Impact Statement. A statement documenting compliance with the cost recovery policy. Only those agencies with significant cost recovery arrangements must prepare a CRIS.
DoHA	Department of Health and Ageing
DSEWPaC	Department of Sustainability, Environment, Water, Population and Communities
EIP	Early Introduction Permit
EOP	(controlled use) Export Only Permit
Existing Chemicals	Existing chemicals are those industrial chemicals available for use in Australia. They include all the chemicals that are listed on the Australian Inventory of Chemical Substances (AICS).
<i>FMA Act</i>	<i>Financial Management and Accountability Act 1997</i>
FSANZ	Food Standards Australia New Zealand
GFC	Global Financial Crisis
HVICL	High Volume Industrial Chemicals List – a list of industrial chemicals that are manufactured and imported in Australia in large quantities (>1000 tonnes).
<i>IC(NA) Act</i>	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i>

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IGCC	Industry Government Consultative Committee (NICNAS) – primary advisory group for industry and government on NICNAS matters; among other things, review the utilisation of resources against NICNAS objectives under the terms of reference set by the Minister
LRCC	Low Regulatory Concern Chemicals – industrial chemicals which could qualify for reduced regulation on the basis of a definition of low risk, or where regulatory input from elsewhere is sufficient to meet Australian requirements
LTD	Limited notification
LVC	Low Volume Chemical permit
LVCR	Low Volume Chemical permit Renewal
New Chemicals	New chemicals are industrial chemicals that are not listed on the Australian Inventory of Chemical Substances (AICS) or chemicals whose importation and/or manufacture are subject to a condition of use.
NICNAS	National Industrial Notification and Assessment Scheme
PEC	Priority Existing Chemical – chemical declared by the Minister for assessment under the NICNAS Existing Chemicals Program because its manufacture, handling, storage, use or disposal gives rise or may give rise to an adverse risk to human health and/or the environment
PIC	Prior Informed Consent (refers to Rotterdam Convention)
PLC	Polymer of Low Concern notification
QSAR	Quantitative Structure Activity Relationship
Register of Industrial Chemical Introdurers	Register containing the name, address and registration number of each person or company introducing relevant industrial chemicals during a year
Rotterdam Convention	The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, ratified by Australia on 20 May 2004
SANHC	Self-Assessment for Non-Hazardous Chemical notification
SANHP	Self-Assessment for Non-Hazardous Polymer notification
SAPLC	Self-Assessment for Polymer of Low Concern notification
STD	Standard notification
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TAG	Technical Advisory Group (NICNAS)
TGA	Therapeutic Goods Administration
WPI	Wage Price Index

# 1 OVERVIEW

## 1.1 Purpose

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has undertaken a review of cost recovery arrangements as recommended by the Australian Government Cost Recovery Guidelines (the Cost Recovery Guidelines). The review looked at the:

- appropriateness of cost recovery,
- design of cost recovery charges to minimise any under/over recovery, and
- adequacy of monitoring arrangements.

The purpose of this Cost Recovery Impact Statement (CRIS) is to transparently demonstrate compliance with the Cost Recovery Guidelines and to outline proposed changes to the existing cost recovery arrangements based on review outcomes. Key proposed changes include:

- better alignment of fees with the costs associated with delivering the services, which includes the introduction of some new fees for service, the reclassification of some existing fees and the abolishment of those fees no longer relevant;
- amending the annual registration charge tier structure to provide a more equitable structure; and
- recovering the cost of stage one of the accelerated assessment and prioritisation of existing chemicals.

A Better Regulation Ministerial Partnership between the Minister for Health and Ageing and the Minister for Finance and Deregulation was announced on 8 September 2011 to evaluate and make recommendations on the regulatory settings for the notification, assessment and regulation of industrial chemicals, noting that any proposed changes to the regulatory arrangements for industrial chemicals should not weaken human health and environment protection. The partnership will also examine the operating arrangements and business processes of NICNAS and recommend reform actions. If there are material changes to the NICNAS cost recovery arrangements as a result of the partnership recommendations, the current CRIS will be amended or a new CRIS will be developed.

## 1.2 Background

### 1.2.1 About NICNAS

NICNAS is the Australian Government's regulatory scheme for industrial chemicals. It was established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989 (IC(NA) Act)* to aid the protection of people at work, the public and the environment from the harmful effects of industrial chemicals. NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used and/or released to the environment. NICNAS also assesses those chemicals that are already in use in Australia on a priority basis. NICNAS aims to ensure the safe use of industrial chemicals by making risk assessment and safety information on chemicals and their potential worker, public health and environmental risks widely available.

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NICNAS is a statutory scheme within the Department of Health and Ageing (DoHA) and contributes to Outcome 1, Population Health - a reduction in the incidence of preventable mortality and morbidity in Australia, including through regulation and national initiatives that support healthy lifestyles and disease prevention. Through NICNAS the Australian Government aims to ensure that uses of industrial chemicals are safe for human health and the environment, and to further improve the efficiency of the regulatory framework for industry and the community.

NICNAS has the mandate to assess new and existing industrial chemicals under the framework set out in the *IC(NA) Act*. The Act provides for:

1. a national system of notification and assessment of industrial chemicals for the purposes of:
  - a) aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals;
  - b) providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals;
  - c) giving effect to Australia's obligations under international agreements relating to the regulation of chemicals; and
  - d) collecting statistics in relation to the chemicals;
2. national standards for cosmetics imported into, or manufactured in, Australia and the enforcement of those standards.

There are four national chemicals assessment and registration schemes which cover food, industrial chemicals, pharmaceuticals and agricultural and veterinary chemicals ([Figure 1](#)). The schemes operate in a complementary manner to ensure there is no duplication or any unnecessary regulatory burden on industry. Industrial chemicals are defined in the context of their use and by their exclusion as therapeutic goods (regulated by the Therapeutic Goods Administration (TGA)), food/food additives (regulated by Food Standards Australia New Zealand (FSANZ)), or pesticides and veterinary medicines (regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA)). While the *IC(NA) Act* concerns introduction of industrial chemicals, state and territory government agencies regulate their control of use, release and disposal.

The scope of the NICNAS risk assessment comprises three elements: occupational health and safety (OHS), public health and environmental protection over the full life cycle of the chemical. NICNAS performs the public health and occupational health and safety assessments in-house. The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) conducts the corresponding environmental assessment for NICNAS. The information from NICNAS assessments is available to state and territory agencies and other federal agencies to assist in regulating the control of use, release and disposal of industrial chemicals and to support the wide range of chemicals management legislation for the protection of human health and the environment.

The *IC(NA) Act* also gives effect to Australia's obligations under international agreements through regulatory powers to prohibit or restrict the introduction or export of industrial chemicals. NICNAS implements import and export restriction for industrial chemicals listed under the Rotterdam Convention. Liaison with state/territory regulatory agencies facilitates the coordination of information at a national level enabling Australia to meet its obligations for notifying the Convention of any chemicals that are banned or severely restricted. Consistent with the requirements under the Stockholm Convention, NICNAS takes into account persistence, bioaccumulation and toxicity characteristics of chemicals when conducting assessments on new and existing chemicals.

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**Figure 1: National Chemical Assessment and Registration Schemes**

	<b>Industrial Chemicals</b>	<b>Agricultural and Veterinary Chemicals</b>	<b>Medicines and Medicinal Products</b>	<b>Food additives, contaminants and natural toxicants</b>
<b>AGENCY</b>	National Industrial Chemicals Notification & Assessment Scheme (NICNAS)	Australian Pesticides & Veterinary Medicines Authority (APVMA)	Therapeutic Goods Administration (TGA)	Food Standards Australia New Zealand (FSANZ)
<b>MINISTRY</b>	Health & Ageing	Agriculture, Fisheries and Forestry	Health & Ageing	Health & Ageing
<b>SCOPE</b>	Assessment only, not Product Registration	Assessment, Product Registration, Quality Assurance & Compliance	Assessment & Product Registration	Assessment & Product Registration
<b>RELEVANT LEGISLATION</b>	Industrial Chemicals (Notification & Assessment) Act 1989.	Agricultural and Veterinary Chemicals (Administration) Act 1992  Agricultural and Veterinary Chemicals Act 1994  Agricultural and Veterinary Chemicals Code Act 1994  Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994	Therapeutic Goods Act 1989	Food Standards Australia New Zealand Act 1991 Australia New Zealand Food Standards Code
<b>ABOUT THE CHEMICALS</b>	Industrial chemicals are varied and cover, for example, dyes, solvents, adhesives, plastics, laboratory chemicals, paints, as well as chemicals used in cleaning products and cosmetics and toiletries.	Agricultural products include chemicals which generally destroy/repel pests or plants. Veterinary products are used to prevent, diagnose or treat diseases in animals.	Therapeutic goods include prescription and non-prescription (including over-the-counter and complementary medicines), as well as medical devices (including some sterilants and disinfectants).	Chemicals are added to food to assist in food processing or to achieve a technological purpose in the food, for example, colouring or flavouring. Other chemicals may occur naturally in food or be present as a result of contamination.

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Under the *IC(NA) Act* NICNAS collects statistics and other information on industrial chemicals such as those used in high volumes in Australia and makes this information publicly available. NICNAS also collects use information on specific industrial chemicals and information on the volumes and adverse health and environmental effects (if any) of chemicals introduced under exemptions, permits and self assessments. A summary of this information is published in NICNAS Annual Reports.

NICNAS also collaborates with a range of national agencies with specific responsibilities within the overall industrial chemicals regulatory framework. These include:

- The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) on environment related issues arising from industrial chemicals;
- The Australian Customs and Border Protection Service (within the Attorney General's portfolio) for reviewing importation records on industrial chemicals;
- The Australian Competition and Consumer Commission (within the Treasury portfolio) on product safety matters;
- Safe Work Australia (within the Department of Education, Employment and Workplace Relations portfolio) on occupational health and safety related issues arising from industrial chemicals;
- The Attorney General's Department for managing chemicals of security concern; and
- The Poisons Scheduling Secretariat (within the Department of Health and Ageing) on public health related issues arising from industrial chemicals.

### 1.2.2 NICNAS Program Structure

NICNAS is organised internally into seven programs to enable achievement of the agency objective.

#### **New Chemicals:**

Ensures that Australians benefit from the protection of human health and the environment in the use of New Chemicals (chemicals not listed on the Australian Inventory of Chemical Substances). This is achieved through:

- assessment of New Chemicals prior to importation or manufacture and issuing of certificates or permits under the *IC(NA) Act* with recommendations to ensure safe use, unless they are exempt from assessment under the *IC(NA) Act*;
- recommendations for risk management to standard setting bodies, e.g., public health controls are achieved, where relevant, through recommendations to the Secretary of the Department of Health and Ageing (or delegate) for inclusion of the chemical on the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP);
- publically available assessment reports for use by all stakeholders including other Australian Government and state and territory public health agencies, occupational health and safety agencies, environmental agencies, transport and consumer product safety agencies; and
- international partnerships to share experiences and resources, to minimise duplication and improve service.

### **Existing Chemicals:**

Ensures that Australians benefit from the protection of human health and the environment in the use of Existing Chemicals (chemicals listed on the Australian Inventory of Chemical Substances). This is achieved through:

- assessment of Existing Chemicals on a priority basis in response to concerns about their health or environmental effects, or both, and making recommendations on the safe use of these chemicals;
- recommendations for risk management to standard setting bodies, (refer to example under New Chemicals above);
- publically available assessment reports for use by all stakeholders including other Australian Government and state and territory public health agencies, occupational health and safety agencies, environmental agencies, transport and consumer product safety agencies;
- creating safety information sheets on assessed Existing Chemicals for use in the workplace, general information sheets on chemicals regulation and information sheets that address issues on specific existing chemicals or groups of chemicals; and
- implementing recommendations from the Existing Chemicals Program Review (*Promoting safer chemical use: towards better regulation of chemicals in Australia. Final report and recommendations*, NICNAS, December 2006).

### **Science Strategy and International:**

Ensures that Australians benefit from the protection of human health and the environment in the use of industrial chemicals. This is achieved through:

- enhancing technical assessment capabilities across assessment teams by reviewing testing methodologies and predictive modeling techniques, benchmarking risk assessment processes and practices;
- providing technical advice on international matters to other government agencies, as appropriate; and
- developing international partnerships to share experiences and resources, to minimise duplication and improve service.

### **Compliance and Enforcement:**

Ensures that Australians benefit from the safe use of industrial chemicals in Australia. This is achieved through:

- developing and maintaining an effective and proactive compliance strategy;
- ensuring that manufacturers, importers and exporters of industrial chemicals are aware of and exercise their responsibilities under the *IC(NA) Act*; and
- maintenance of the Register of Industrial Chemical Introducers and implementing the NICNAS registration program.

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### **Reform:**

Ensures that Australians benefit from the safe use of industrial chemicals in Australia. This is achieved through:

- enhancing the efficiency and effectiveness of the NICNAS regulatory framework;
- benchmarking reforms to the NICNAS regulatory framework against national and international best practice;
- ensuring an appropriate balance between reduction in regulatory burden on industry and maintaining or enhancing health, safety and environmental standards through reforms to the framework; and
- maintenance of the Australian Inventory of Chemical Substances (AICS).

### **Business Management and Communications (organizational support activities):**

Provides support to other NICNAS programs with coordination of parliamentary responsibilities, financial management, facilities management, committees coordination, stakeholder communications, publications and website management.

### **Regulatory Strategy (Corporate):**

Provides corporate governance, maintains linkages with policy partners and other relevant government departments, and contributes to whole of government initiatives aimed at increasing efficiency of chemicals and plastics regulation.

### **1.2.3 Funding arrangements**

NICNAS is fully funded through cost recovery with fees and charges prescribed in the *IC(NA) Act* and regulations made under the *IC(NA) Act*. Associated enabling legislation includes the *Industrial Chemicals (Registration Charges – General) Act 1997*, the *Industrial Chemicals (Registration Charges – Customs) Act 1997* and the *Industrial Chemicals (Registration Charges – Excise) Act 1997*.

Full recoveries of the NICNAS costs from industry were provided for in the 1994-95 Budget under “Implementing full cost recovery in 1996-97 for National Industrial Chemicals Notification and Assessment Scheme”<sup>1</sup>. A small appropriation from the Government to subsidise the compliance program to support small to medium enterprise comply with the Scheme and funding to cover the cost of services to government that relate to the regulation of industrial chemicals was ceased in June 2005, as detailed in the NICNAS 2005 CRIS.

NICNAS recovers the full cost of its regulatory activities through fees and charges for services provided to industrial chemical importers and manufacturers, except for a minor appropriation from government by way of a notional interest payment on the balance of cash/Official Public Account holdings.

Most of NICNAS’s operational income is collected from registrants (introducers) of industrial chemicals. Registrants pay an administration fee to be listed on the Register of Introducers of

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<sup>1</sup> Portfolio Budget Measures Statements 1994-95, Industrial Relations Portfolio, Budget Initiatives and Significant Changes in Appropriations 1994-95, Budget Related Paper No. 4.11.

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Industrial Chemicals and a levy based on the introduction value of the industrial chemicals. NICNAS also collects fees for over 30 separate fee for service items from new industrial chemical notifiers, holders of confidence and other parties, based on fee schedules in accordance with the administered regulations, and other charges.

Updates to NICNAS fees and charges are determined annually in consultation with the NICNAS Industry Government Consultative Committee (IGCC). The IGCC was established in 1997 to (amongst other things) review the utilisation of resources against NICNAS objectives, review the performance of NICNAS and develop strategies for improving the efficiency and effectiveness of NICNAS operations. The IGCC gives industry the opportunity to provide input into the NICNAS planning process and provides a forum for discussion of NICNAS's performance.

### **1.2.4 Approach to cost recovery review**

A structured approach was used to review the current cost recovery arrangements. Independent consultants were engaged by NICNAS to undertake an Activity Based Costing (ABC) study which provided an up-to-date analysis of the costs associated with the pre-market assessment and other regulatory activities of NICNAS. This study looked at the costs of the activities as currently undertaken by NICNAS over the 12 month period 1 April 2009 to 31 March 2010. The findings from the ABC study were reviewed and reconfirmed in May 2011.

Concurrently, NICNAS provided a discussion paper to stakeholders regarding its cost recovery activities, to identify concerns with the current arrangements, activities that had changed significantly since the last CRIS and likely changes in activity over the coming years. Face to face stakeholder consultation meetings were held in both Sydney and Melbourne (in addition to on-going consultative processes such as the IGCC). An on-line survey was used to complete the stakeholder consultation process. Individual submissions received are available on the NICNAS website ([www.nicnas.gov.au](http://www.nicnas.gov.au)). A summary of the feedback received through written submissions and the on-line survey process as well as NICNAS's response is available in Appendix A.

### **1.3 Australian Government Cost Recovery Policy**

In December 2002 the Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources. The underlying principle of the policy is that entities should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group and where charging is consistent with Australian Government policy objectives. Cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the Australian Government Cost Recovery Guidelines (Cost Recovery Guidelines).

The policy applies to all *Financial Management and Accountability Act 1997 (FMA Act)* agencies and to relevant *Commonwealth Authorities and Companies Act 1997 (CAC Act)* bodies that have been notified. In line with the policy, individual portfolio ministers are ultimately responsible for ensuring entities' implementation and compliance with the Cost Recovery Guidelines.

### **1.3.1 What is cost recovery?**

The Cost Recovery Guidelines state that cost recovery is the recovery of some or all the costs of a particular activity. Australian Government cost recovery charges fall into two broad categories:

- fees for goods and services; and
- ‘cost recovery’ taxes (primarily levies, but also some excises and customs duties).

Cost recovery is different from general taxation. Some levies or taxes are used to raise cost recovery revenues, but the direct link – or ‘earmarking’ – between the revenue and the funding of a specific activity distinguishes such cost recovery taxes from general taxation. General taxation, on the other hand, is a compulsory exaction of money by a public authority for public purpose, enforceable by law, and which is not a payment for services rendered.

### **1.3.2 Why is cost recovery important?**

According to the Cost Recovery Guidelines, used appropriately, cost recovery can provide an important means of improving the efficiency with which Australian Government products and services are produced and consumed. Charges for goods and services can give an important message to users or their customers about the cost of resources involved. It may also improve equity by ensuring that those who use Australian Government products and services or who create the need for regulation bear the costs.

## 2 ANALYSIS OF ACTIVITIES

### 2.1 Overview

This section aims to assess the appropriateness of cost recovery arrangements for each of NICNAS's activities. The Guidelines categorise activities undertaken by Australian Government agencies into:

- regulatory activities, those activities involved in administering regulations; and
- information activities, activities involving the collection, compiling and disseminating information and any other activities of a non-regulatory nature.

Regulatory activities are further classified as pre-market or post-market regulation activities. This classification and the relevance to NICNAS are described in Table 1.

**Table 1: NICNAS's Activities by category**

Activities		Relevance to NICNAS
Pre-market regulatory activities	Registration and approvals (e.g. approvals and permits, testing, licensing and registering products)	<ul style="list-style-type: none"> <li>• Registration to introduce relevant industrial chemicals (annual registration)</li> <li>• Assessments of new chemicals for approval to introduce (certificates and permits) and immediate AICS listing of chemicals assessed under certificate categories (if requested)</li> <li>• Prior informed consent to import/export certain hazardous chemicals under the Rotterdam Convention</li> </ul>
	Issuing exclusive rights and privileges (e.g. patents)	Not performed by NICNAS
Post-market regulatory activities	Monitoring ongoing compliance and regulations	<ul style="list-style-type: none"> <li>• Assessment of existing chemicals</li> <li>• Monitoring of post-introduction reporting (annual reporting)</li> <li>• Audit activities</li> <li>• Collection of Statistics e.g., High Volume Industrial Chemicals List (HVICL)</li> <li>• Listing on AICS of chemicals assessed under certificate categories</li> </ul>
	Investigation and enforcement	<ul style="list-style-type: none"> <li>• Case investigations</li> <li>• Prosecutions</li> </ul>
Information activities		<ul style="list-style-type: none"> <li>• Website</li> <li>• Publications</li> <li>• Presentations and seminars</li> <li>• Consultative committees</li> <li>• Informing policy</li> <li>• Parliamentary servicing</li> <li>• Implementing reform</li> <li>• International harmonisation</li> </ul>

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Each of NICNAS's activities are analysed below according to the set of questions outlined in the Cost Recovery Guidelines to determine whether cost recovery is appropriate.

### 2.2 *Pre-market regulatory activities*

#### 2.2.1 Description

##### *Registration to introduce relevant industrial chemicals (annual registration)*

Anyone who wishes to introduce relevant industrial chemicals into Australia, through importation or manufacture, must register with NICNAS and be placed on the Register of Industrial Chemical Introducers as set in Part 3A of the *IC(NA) Act*. The registration process requires all businesses that manufacture or import relevant industrial chemicals subject to the Act to apply or renew their registration details each year and ensure that they are registered with NICNAS at the appropriate tier. The process of registration is covered with a registration fee set to cover the administrative cost of establishing and maintaining the registration.

##### *Assessments of new chemicals for approval to introduce (certificates and permits)*

Anyone who wishes to introduce a New Chemical into Australia, through importation or manufacture, must notify NICNAS and obtain approval before the industrial chemical can be supplied, sold, distributed and used in Australia, except for some low risk chemicals which are exempt from notification requirements within strict parameters. When notifying NICNAS, introducers of new industrial chemicals can choose from several notification categories (including certificates, permits and self-assessments).

NICNAS assessment identifies potential risks to occupational health and safety, public health, and the environment that may be associated with manufacture, formulation, use, storage and disposal of the chemical. NICNAS also makes recommendations on appropriate risk management (control) measures. The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) performs the environmental components of the relevant assessments on a fee for service basis, which NICNAS includes in the fees charged to industry.

The *IC(NA) Act* specifies data requirements for individual permit and certificate categories and outlines the assessment process and contents of assessment reports. In general certificate applications require a more comprehensive data set than permit applications and, consequently, permissible introduction volumes and durations are usually greater under certificates than permits. Within certificate categories, the nature of the chemical and proposed annual introduction volumes generally dictate the assessment category and hence the data set required. There are three main certificate categories: standard (STD), limited (LTD) and polymers of low concern (PLC). Chemicals assessed under certificate categories are listed on the Australian Inventory of Chemical Substances (AICS) five years after assessment, unless the company requests immediate listing. Once the chemical is listed on the AICS, it is available for widespread use within use conditions, where specified.

Examples of permits include commercial evaluation (CEC), low volume chemical (LVC), controlled use (CUP), and early introduction (EIP). Chemicals assessed under permit categories are not added to the AICS.

Self-assessment Notifications are available for non-hazardous chemicals and polymers.

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When an application for a permit or certificate is submitted, NICNAS first analyses the data package for completeness of the data, any inconsistencies, and whether the level of detail is sufficient for an adequate risk assessment to be performed. Further data and/or clarification are requested at the screening stage when needed. Based on information supplied by the applicant, NICNAS undertakes a scientific assessment, which entails evaluating the chemical identity, the predicted hazard and the extent of exposure/release, to determine the level of risk to workers, the public and the environment posed by the new chemical over its lifecycle. A certificate or permit is issued to allow introduction.

For chemicals assessed under the certificate system, NICNAS prepares an assessment report for publication which includes the risk assessment (but omitting any confidential (exempt) information), as well as recommendations for the safe use of the chemical. Permits are issued with conditions related to safe use and brief details of new permits are published in the *Chemical Gazette* (but omitting any confidential (exempt) information).

Some low risk chemicals are exempt from notification to NICNAS even if they are new industrial chemicals (Part 3, Section 21 of the *IC(NA) Act*). For most exemption categories no action is required prior to introduction, but they have an annual reporting obligation (see 2.3 Post-market regulatory activities). Some exemption categories, for example the manufacture or importation of a new chemical for cosmetic use at 10 kg to 100 kg per annum under subsection 21(4)(b)(i) of the *IC(NA) Act*, require advice of intent to introduce under exemption. When NICNAS receives advice of intent to introduce under exemption from an introducer, NICNAS first checks the registration status of the company, then the information submitted against the various (approximately 12) criteria for introduction. If there are no concerns, a letter is generated to advise the introducer of receipt. Where concerns exist, the advice of intent to introduce is referred to the New Chemicals program for assessment against the criteria, after which the introducer is informed in writing of receipt of the advice or that the chemical is not suitable for introduction under s21(4) of the *IC(NA) Act* (approximately 5% of exemption advices received require this step).

Companies or individuals who hold a certificate or permit for industrial chemicals must notify NICNAS of any significant change or proposed change to the function or use, method of manufacture, or increased introduction amount of the industrial chemical. A company or individual is also required to advise NICNAS where additional information has become available on adverse health or environmental effects of the chemical, or other circumstances noted on the assessment report for the chemical have occurred. NICNAS will then make a determination if the changed circumstances require further assessment and a secondary notification.

### *Prior informed consent to import/export certain hazardous chemicals under the Rotterdam Convention*

Importers and exporters of certain hazardous industrial chemicals are required to first seek authorisation from NICNAS under the Rotterdam Convention (which Australia has ratified) (Part 6, Section 106 of the *IC(NA) Act* and Regulation 11C of the *IC(NA) Regulations 1990*). Under the Rotterdam Convention, countries nominate chemicals which have been severely restricted or banned in their country. Once approved for inclusion in the Prior Informed Consent (PIC) procedure, these chemicals will be subject to controls in international trade. As a party (participating country) to the Rotterdam Convention, Australia must ensure that chemicals listed in the Convention are not exported to countries that do not wish to receive them. NICNAS is responsible for implementing Australia's obligations for industrial chemicals.

The steps that NICNAS undertakes to process PIC applications are:

- Advise importer/exporter of obligations and process for authorisation and/or export notification;

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- Receipt authorisation application and/or notification;
- Determine destination country's status with regard to the Rotterdam Convention (i.e., whether the destination country is a participating country, and their import decision and correlating consent conditions on chemicals listed in Annex III of the Convention);
- Liaise with DSEWPaC (Australia's Designated National Authority for the Rotterdam Convention) where explicit consent is required or export is subject to notification;
- Complete authorisation checklist (liaising with exporter where required);
- Make recommendation to authorise/not authorise import/export; and
- Inform applicant of decision and provide written authorisation where applicable;

Export notifications require administrative vetting by both NICNAS and DSEWPaC within 30 days of receipt.

NICNAS currently recovers the costs of processing PIC applications via the registration charge (levy). NICNAS proposes to introduce a fee for service for PIC applications. Given the timing for legislative amendments required to implement this change, the fee for PIC applications is proposed to commence in 2012-13 (see section 4.1.2).

### 2.2.2 Policy Review

*Will other firms be able to free ride on the approval of the first applicant?*

NICNAS Registration is the application by importers and manufacturers in Australia to introduce (import and/or manufacture) relevant industrial chemicals. Once a company is registered, its name and registration number are placed in the Register of Industrial Chemical Introducers. If a business does not have a NICNAS Registration and imports and/or manufactures industrial chemicals, then they are in breach of the *IC(NA) Act*. The Act allows NICNAS to stop the business from introducing industrial chemicals until they have met the requirements of the Act.

A New Chemical may only be introduced to Australia by a certificate or permit holder, except for some low risk chemicals which are exempt from notification requirements within strict parameters. If another business (not a current certificate or permit holder) wants to introduce a New Chemical they must a) notify NICNAS, b) seek an extension to the original assessment certificate or c) transfer the assessment certificate from original holder under specific circumstances. Options b and c require agreement of the original notifier. If a second notification for the same chemical is received by NICNAS this will be treated as if it is a new notification and will be assessed and charged accordingly. Under such circumstances NICNAS will make no reference to the information, assessment and/or determinations associated with the first notification of that chemical.

Each company wishing to import or export an industrial chemical listed under the Rotterdam Convention must seek authorisation from NICNAS. This authorisation is issued to individual companies and is non-transferable.

*Is charging consistent with policy goals?*

Charging is consistent with policy goals because:

- Introducers benefit through registration of their company which allows them to legally introduce relevant industrial chemicals into Australia;

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- Notifiers benefit through the assessment of their chemical which allows their chemical to be supplied, sold, distributed and used in Australia; and
- Exporters and importers of industrial chemicals listed under the Rotterdam Convention benefit from authorisation to export and/or import.

Assessment of industrial chemicals also benefits workers, consumers and the general public through assurance that chemicals introduced into Australia are safe when used as directed.

The Cost Recovery Guidelines state that fees might be needed to discourage frivolous or vexatious demand and to signal to users the costs of resources involved. If a fee for New Chemical notifications was not in place a company may be more likely to lodge a speculative application tying up resources at NICNAS. In addition, NICNAS's screening framework for New Chemical assessment applications discourages notifications that do not contain the supporting data required for an adequate risk assessment. NICNAS proposes to introduce a screening fee for all New Chemical application fee for service activities commencing in 2012-13 (see Section 4.1.3).

*Is charging efficient and cost effective?*

A fee for company registration, New Chemical notifications, and PIC would be efficient and cost effective because:

- It is possible to establish a fee that accurately links the costs of the activities to the regulated firms or individuals; and
- The fee is administratively simple to collect because it is possible to identify and bill each regulated firm or individual.

### **2.2.3 Conclusion**

There have been a number of improvements in the New Chemicals assessment program over the last five years. For example, through the Low Regulatory Concern Chemicals (LRCC) reform initiative a number of lower cost assessment products were introduced for chemicals that meet LRCC criteria. This has resulted in a greater range of assessment products requiring varying amounts of data and assessment effort, and better alignment of assessment effort (and therefore cost) with the risk posed by these chemicals. The potential savings to industry based on a comparison of the costs of the categories available before the LRCC reforms, was greater than \$500,000 in 2009-10<sup>2</sup>.

An industry evaluation of the first tranche of the LRCC reforms was undertaken in 2009. In general, industry stakeholders were positive about the direction of the reform provisions and that the reforms represent an improvement ('a step in the right direction'). Tangible benefits to industry are demonstrated by an increase in the use of exemptions (Appendix C).

Cost recovery through a fee for service for these pre-market regulatory activities is appropriate because there is no capacity for other entities to free ride on the approval of the first applicant until the chemical is listed on the AICS, charging is consistent with policy goals, and charging is efficient and cost effective. Regulatory fees incurred by the introducer would form part of the cost of bringing products to the market and would be expected to be passed through to the consumer in product prices.

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<sup>2</sup> NICNAS Annual Report 2009-10.

## **2.3 Post-market regulatory activities**

### **2.3.1 Monitoring ongoing compliance with regulations**

#### **2.3.1.1 Description**

##### *Assessment of existing chemicals*

NICNAS conducts an existing chemicals review program that includes targeted assessments, Priority Existing Chemical (PEC) assessments (full and preliminary), secondary notifications and reviews of international assessments submitted through the OECD Program. Some of these international hazard assessments are adopted by NICNAS when conducting national reviews of these chemicals to avoid duplication.

PEC assessments are comprised of assessment modules, with the modular make-up of each assessment varying depending on its scope. The modules are hazard assessment, exposure assessment, environment assessment, human health assessment, and recommendations. Due to the large number of chemicals on AICS (approximately 39,000), NICNAS assesses existing chemicals on a priority basis in response to concerns about their health and/or environmental effects. Any person or organisation with a concern about the public health, occupational health and safety, or environmental effects of an industrial chemical may nominate a chemical for assessment.

There are four possible outcomes from NICNAS assessments for existing chemicals:

- Recommendations to other agencies to implement control measures
- Recommendation and subsequent regulatory action by NICNAS through annotation of the chemical on the AICS
- Recommendations to industry on the safe use of the chemical
- Dissemination of chemical safety information

The purpose of the assessments of Existing Chemicals is to ensure that industrial chemicals in use do not pose unacceptable risks to human health and safety or the environment. NICNAS registrants potentially benefit from the assessment of existing chemicals through continued consumer confidence and the provision of information to assist in meeting their obligations under commonwealth, state and territory legislation. Workers, consumers, the general public and the environment also benefit through assurance that the chemical does not pose unacceptable risks to human health and safety or the environment.

In 2006 NICNAS undertook an independent review of the Existing Chemicals program. The review made 23 recommendations grouped into five key reform drivers:

- Better engagement and communication;
- Enhanced mechanisms to identify chemicals of concern; new screening processes;
- Improving efficiency;
- Targeted assessments; and
- Increasing legislative reach: enhanced control powers.

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To date, NICNAS has progressed some of these recommendations including developing options for a framework to screen all Existing Chemicals; enhancing staff capability in simulation techniques through formal training in Quantitative Structure Activity Relationships; and entered into formal bilateral arrangements with Canada and the USA and a Memorandum of Understanding with the European Chemicals Agency. These reforms have resulted in a more efficient way of assessing existing chemicals, resulting in savings to industry.

### *Secondary Notifications*

Where a chemical listed on AICS has been previously assessed by NICNAS and the circumstances under which the chemical was originally assessed changes significantly (e.g., function or use of the chemical, amount to be introduced or new information on adverse effects on human health and/or the environment) NICNAS is required to assess the significance of the changed circumstances and if required undertake a re-assessment of the chemical as a secondary notification.

### *Monitoring of post-introduction reporting (annual reporting)*

Under sections 21AA and 40N of the *IC(NA) Act* a person introducing a new industrial chemical under certain permits, certificates or exemptions is required to provide a report to the Director, NICNAS stating the name and quantity of the chemical that was introduced during the previous reporting year (1 September – 31 August). Where a person is issued a commercial evaluation permit, low volume permit, controlled use permit, or a self-assessed assessment certificate, the report must also include any additional information about known adverse effects of the chemical on occupational health and safety, public health or the environment which may have come to the introducer's attention.

Annual reports are required by 28 September every year and ensure the ongoing health, safety and environmental protection from new industrial chemicals introduced to Australia either without a NICNAS assessment or with an assessment requiring a lower overall level of health and environmental data. Under section 21AB of the *IC(NA) Act* the Director, NICNAS must publish a summary of the information provided at least once during the next registration year in the Chemical Gazette.

To assist companies with annual reporting, an online Annual Reporting Module has been developed and enables organisations with annual reporting obligations to submit reports online via the NICNAS website.

### *Audit activities*

NICNAS undertakes audit activities to ensure the proper and effective administration of the *IC(NA) Act* and ensure that all introducers and the use of industrial chemicals are appropriately regulated within the parameters of the *IC(NA) Act*.

NICNAS may undertake audits regarding the various obligations under the *IC(NA) Act*. They range from desktop auditing to site inspections, and may vary in technical nature depending on the particular aspect of the legislation being audited. NICNAS may require introducers of industrial chemicals to produce documentation to support information provided, or to demonstrate compliance with the legislation. Auditing may be random in order to assess general compliance, may be in response to particular concerns such as failure to meet a reporting obligation, or directed towards a particular industry.

In identifying potential audit recipients, NICNAS will take into account an organisation's compliance history. Companies that have demonstrated a consistently high level of voluntary compliance will be

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audited less frequently than those with a poor record. This is an incentive to organisations to manage their regulatory responsibilities well.

### *Collection of statistics*

NICNAS collects statistics and other information on industrial chemicals such as those used in high volumes in Australia and makes this information publicly available. NICNAS collects use information on specific industrial chemicals and information on the volumes of chemicals introduced under exemptions, permits and self-assessments. NICNAS also collects information on adverse health and environmental effects (if any) of chemicals introduced under permits and self-assessments. This information is published in NICNAS Annual Reports and on the NICNAS website.

### *Listing on AICS*

Chemicals assessed under certificate categories are listed on AICS five years after assessment, unless the company requests immediate listing, through gazetting in the chemical gazette. At the end of five years, the company which is the holder of the certificate for the assessed chemical is given the opportunity to request the chemical is put on the confidential section of AICS.

For a chemical to be listed on the confidential section, an application to NICNAS is required. There are some minimum data requirements for the application. The Director NICNAS, makes the decision in consultation with the NICNAS Technical Advisory Group (TAG) after taking into consideration the public and commercial interests. The commercial interest must outweigh the public interest for the application to be successful. If the application is approved, the chemical is listed on the confidential section for five years. At the end of five years, the company can apply to re-list the chemical for another five years, where the same process is followed.

Once the chemical is listed on the AICS, it is available for widespread use within use conditions, where specified. The public AICS is available to search on the NICNAS website. Searches of the confidential AICS may only be undertaken by NICNAS and require a statement of *bona fide* intent to introduce the chemical into Australia.

### **2.3.1.2 Policy Review**

#### *Is charging consistent with policy goals?*

The assessment of existing chemicals, collection of statistics, auditing, monitoring of post assessment reporting, and listing chemicals on AICS are all activities directly relevant to the objectives of NICNAS.

While the cost of audits and investigations of companies and post-introduction reporting could potentially be recovered directly from the introducer, such action would be counter-productive and impact on the current high-level of self-reported non-compliance (a large proportion of identified instances of non-compliance are self-reported). Likewise, the cost of assessing specific existing chemicals could be charged via a fee for service, but it is not always possible to identify the introducer(s), nor limit the free ride available to introducers who would not be charged for assessing specific existing chemicals. Previous NICNAS experience in charging a fee for this service was not successful as it encouraged firms to temporarily stop introducing the chemical being reviewed in order to avoid the fee.

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The Cost Recovery Guidelines state that where fees are inconsistent with policy goals, the agency should consider imposing levies. Cost recovery charges via a levy would not significantly reduce the effectiveness of the regulation or the level of compliance.

*Is charging efficient and cost effective?*

Costs for these activities are recovered through a levy on introducers of industrial chemicals. An annual levy is administratively simple to collect. Annual levies are payable to NICNAS by August 30 each year.

### **2.3.1.3 Conclusion**

These activities potentially benefit all industrial chemical introducers, end users and the general public by ensuring the safe use of industrial chemicals by making risk assessment and safety information on chemicals and their potential worker, public health and environmental risks widely available. Risk management recommendations are made to standard setting bodies where appropriate.

Cost recovery is appropriate because introducers create the need for the activity through having an industrial chemical in the marketplace.

## **2.3.2 Investigation and enforcement**

### **2.3.2.1 Description**

Investigation and enforcement is an essential part of effective regulation of industrial chemicals and benefits the industry overall by ensuring all relevant companies are compliant (and bearing the costs of regulation) and providing some competitive advantage over non-registered businesses. For example, though not legally obliged to do so, many Australian companies (as part of quality systems or other internal procedures) evaluate potential suppliers against the supplier's regulatory obligations. Such due diligence may result in a NICNAS registered supplier being evaluated more positively by the purchaser than an unregistered (and therefore illegal) industrial chemical introducer.

NICNAS investigations provide industry and the public with certainty that instances of non-compliance are investigated and the offending introducer receives an appropriate regulatory response ranging from education to pecuniary penalties.

### **2.3.2.2 Policy Review**

*Is charging consistent with policy goals?*

Investigation and enforcement is a regulatory activity directly relevant to the objectives of NICNAS.

The charging of fees for investigation and enforcement would be counterproductive. For example, charging individual companies for investigations may discourage them from notifying NICNAS of self-identified breaches. The Cost Recovery Guidelines state that where fees are inconsistent with policy goals, the agency should consider levies if there is an identifiable group that could be levied. Cost recovery charges via a levy would not significantly reduce the effectiveness of the regulation or the level of compliance.

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*Is charging efficient and cost effective?*

Costs for these activities are recovered through a levy on introducers of industrial chemicals. An annual levy is administratively simple to collect. Annual levies are payable to NICNAS on August 31 each year.

### **2.3.2.3 Conclusion**

In 2009 NICNAS's compliance and enforcement framework was published on the NICNAS web site. The aim of the document is to increase the transparency of NICNAS's enforcement approach and thereby assisting in building cooperative relationships with the Australian chemical industry and the community to encourage voluntary compliance. Maximising voluntary compliance is a cost effective and efficient way to achieve the safe use of chemicals in Australia. A high level of voluntary compliance reduces the cost of the NICNAS compliance and enforcement program, resulting in a reduced levy for industry.

Cost recovery is appropriate because charging is consistent with policy goals and is efficient and cost effective.

## **2.4 Information Activities**

### **2.4.1 Description**

#### *Communication and Outreach*

NICNAS provides information on industrial chemicals and industrial chemical regulation through the NICNAS website, corporate publications, consultative committees and answering inquiries. These information products help inform NICNAS's stakeholders of its work in a number of areas such as: recommendations from chemical assessment reports, developments in major projects, emerging national and international concerns about chemical safety, as well as upcoming consultations and events. NICNAS also delivers targeted communications (such as training for notifiers and chemical introducers) to ensure companies are more aware of their legal obligations and health and safety issues relevant to the chemicals in which they trade.

Almost all materials prepared by NICNAS are prepared for those introducing or using industrial chemicals, with others receiving ancillary benefits. The preparation of these materials also enhances the public's confidence in the regulation of industrial chemicals, which benefits the regulated industry. Accordingly, it is appropriate that the costs of these activities should be recovered from the industrial chemical industry. Recovery through the NICNAS registration charge is considered to be cost-effective.

NICNAS's parliamentary servicing functions (such as budget estimates hearings, ministerial briefings) and informing policy are integral to the functions under the *IC(NA) Act*. Parliamentary services are not a significant proportion of NICNAS's costs

#### *International Harmonisation*

NICNAS is involved in information exchanges such as presentations, conferences, and multijurisdictional meetings to advance international regulatory harmonisation. International harmonisation activities facilitate increased understanding and agreement on chemical risk assessment principles and practices within a framework of sustainability. It enables the acceptance of assessments

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and assessment methodology, where comparable assessment standards can be demonstrated. As such, international harmonisation affords benefits to all stakeholders and has the support of government, industry and the community. Some of the benefits are realised through assessment fee reductions and fee waivers for specific assessments (as is the case under the foreign schemes collaboration with Canada), others provide compliance savings for the introducers themselves (for example, standard templates and assessment reports across international borders).

The objectives of NICNAS' international engagement are to:

- implement best practice chemical regulation in Australia based on international experience;
- ensure that NICNAS risk assessments and reports are scientifically robust and consistent with international standards;
- promote international harmonization and cooperation with the aim of minimizing unnecessary duplication of chemical assessment work and undue regulatory burden on Australian industry; and
- influence technical policies, tools and processes developed by international organisations to share resources, to minimise duplication and improve efficiency.

This strategy is progressed through:

- multilateral forums established under the auspices of the Organisation for Economic Cooperation and Development (OECD), United Nations Environment Program (UNEP) and the Asia-Pacific Economic Cooperation (APEC); and
- bilateral arrangements with countries that have comparable, active and successful chemical regulatory programs such as Canada, USA and the European Union.

### *Reform Initiatives*

In line with a commitment for continuous improvement and managing regulatory burden on industry, NICNAS has continued to invest in a significant number of reform initiatives. The program is discussed by the IGCC each year. In recent years, reforms progressed include:

- Low Regulatory Concern Chemicals (LRCC) reform;
- reforms to products at the cosmetic-therapeutic interface;
- recognition of the Canadian New Substances program as an Approved Foreign Scheme under the Act;
- establishing cooperative arrangements with the US Environment Protection Agency (US EPA), European Chemicals Agency (ECHA), and Health Canada/Environment Canada;
- implementation of recommendations from NICNAS's review of its Existing Chemicals program; and,
- reforms to the regulation of industrial nanomaterials.

The industrial chemicals industry is the main beneficiary of these reforms. For example, the LRCC reforms introduced flexibility into the assessment process to enable the fast tracking of low regulatory concern chemicals while maintaining existing levels of worker safety, public health and environmental standards. This resulted in a number of cheaper assessment products, both in terms of reduced assessment fees and fewer data requirements, and additional exemptions for lower risk chemicals.

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The reforms to regulatory arrangements for products at the cosmetic-therapeutic interface reduced confusion for industry regarding the regulation of these products by establishing mechanisms to better differentiate between products to be regulated as cosmetics and those to be regulated as medicines.

Other reforms have benefited industry by enhancing the efficiency and effectiveness of NICNAS's assessment programs. Some of the efficiencies achieved through implementation of the Existing Chemicals reforms are discussed in section 2.3.1.1. Formal recognition of foreign schemes and the establishment of cooperative arrangements have facilitated the streamlining of the NICNAS assessment processes through information sharing with comparable overseas regulators, and access to developments in assessment methodologies and electronic tools.

NICNAS reforms are benchmarked against international best practice and aim to harmonise regulatory requirements with major trading partners, where possible. NICNAS continues to reform its programs in response to stakeholder concerns and emerging issues within the context of the Council of Australian Governments (COAG) principles and guidelines.

### 2.4.2 Policy Review

*Are there public good characteristics?*

Public goods exist where provision for one person means the good or service is available to all people at no additional cost. The Cost Recovery Guidelines state that judgements about public goods consider two characteristics of the product: its level of rivalness and its level of excludability.

NICNAS considers that the public good characteristics of its information activities are not significant enough to make it undesirable to charge for these products.

*Are there significant spillover benefits from the product?*

The Cost Recovery Guidelines state that the spillover benefits need to result directly from the availability of the information, rather than from activities (such as research) that incorporate the information.

While other relevant authorities may use the information provided in NICNAS assessments for analysing and setting risk management strategies, this does not constitute a significant spillover benefit.

### 2.4.3 Conclusion

The information activities undertaken by NICNAS benefit the industrial chemical introducers through provision of information on industrial chemical regulatory arrangements and the effective management of functions under the *IC(NA) Act*.

International harmonisation and NICNAS reform activities support the Government's policy of ensuring regulatory efficiency whilst maintaining health and environmental safety standards. These activities have afforded benefits to the industrial chemicals industry as discussed in section 2.4.1.

As the industrial chemical industry benefits from these activities with no apparent external spill-over, it is appropriate that the costs of these activities should be recovered from introducers. Recovery through the NICNAS annual levy is considered to be cost-effective.

It is the Government's decision that NICNAS is fully cost recovered (see section 1.2.3 for details).

### **3 DESIGN AND IMPLEMENTATION**

According to the Cost Recovery Guidelines, charges can be collected in a variety of ways and based on varying measures of costs. The design of the cost recovery arrangements should include the following principles:

- linking the charge as closely as possible to the activity or product to be cost recovered;
- a system design that is cost effective to calculate, collect and enforce;
- a system design where the compliance costs of paying the charges are not excessive;
- ensuring all aspects of the charging mechanism are consistent with the policy objectives of the agency; and
- a charging system that is consistent with other Australian Government policies.

#### ***3.1 Basis of Charging – Fee or Levy***

Cost recovery charges can be collected using:

- a fee that charges individuals or firms directly for the cost of providing the activity; or
- a levy established using a tax Act on a group of individuals or firms.

The Cost Recovery Guidelines state that when cost recovery is appropriate, charges should be based on fees, as long as they are efficient, cost effective and consistent with the policy objectives of the agency. Because they are not so closely linked to the costs of individual activities, levies do not have the efficiency advantages of fees. It is desirable, where possible, to charge for activities directly through fees. Where levies are used, they should be closely linked to costs and focused on recovering costs from only those groups of firms or individuals that use the products or services or create the need for regulation.

Consistent with the Cost Recovery Guidelines, NICNAS charges fees for service where a direct relationship between the activity and a fee can be made. The costs are driven by the applicant and the benefits that arise from these activities are limited to the applicant. A list of fees is contained in Section 3.5 – Summary of charging arrangements.

An annual levy is imposed on introducers of industrial chemicals above a threshold. This levy pays for activities that regulate the industry as a whole (e.g. existing chemicals assessments, post-market monitoring, and statistical collection) and information activities. These costs are driven by the regulation of the market and may not relate to activities performed for one or other introducer.

#### ***3.2 Legal Requirements for the Imposition of Charges***

The legal authority for pre-market fees are detailed in Section 110 of the *IC(NA) Act*, with amounts specified in Regulation 13 and Schedule 2.

Legal authority for the annual levy (registration charge), which is considered a tax, is included in the *Industrial Chemicals (Registration Charges - General) Act 1997*. Section 80S of the *IC(NA) Act* provides for the imposition of a registration charge for excise, customs or taxation purposes. Section 3

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of the *Industrial Chemicals (Registration Charges - General) Act 1997* provides for the imposition of the registration charge as a levy. The amount of the registration charge is based on tiers prescribed in Section 80T of the *IC(NA) Act* and is based on the value of industrial chemicals introduced, with the level of charge payable included in Regulation 11AB.

### **3.3 Costs to be Included in Charges**

For regulatory products or services, cost recovery charges ideally should reflect as closely as possible the costs of undertaking individual activities.

NICNAS uses an activity based costing (ABC) methodology for the assignment and allocation of all direct, indirect and overhead costs to its activities. The methodology allows costs to be allocated to activities based on their consumption at each stage of the process through to the final product or service. Activity based costing facilitates product costing and pricing, cost analysis and management, resource planning and performance reporting. An independent consultant was engaged to undertake the activity based costing analysis on behalf of NICNAS.

NICNAS undertakes continuous time recording for all staff. NICNAS has been maintaining this Resource Allocation System (RAS) for a number of years. These data were used to inform the ABC study, with staff questionnaires developed to validate this information as well as capture time spent on some activities not contained within the RAS activity dictionary. Labour costs are based on DoHA's Certified Agreement, plus appropriate allowances for on-costs.

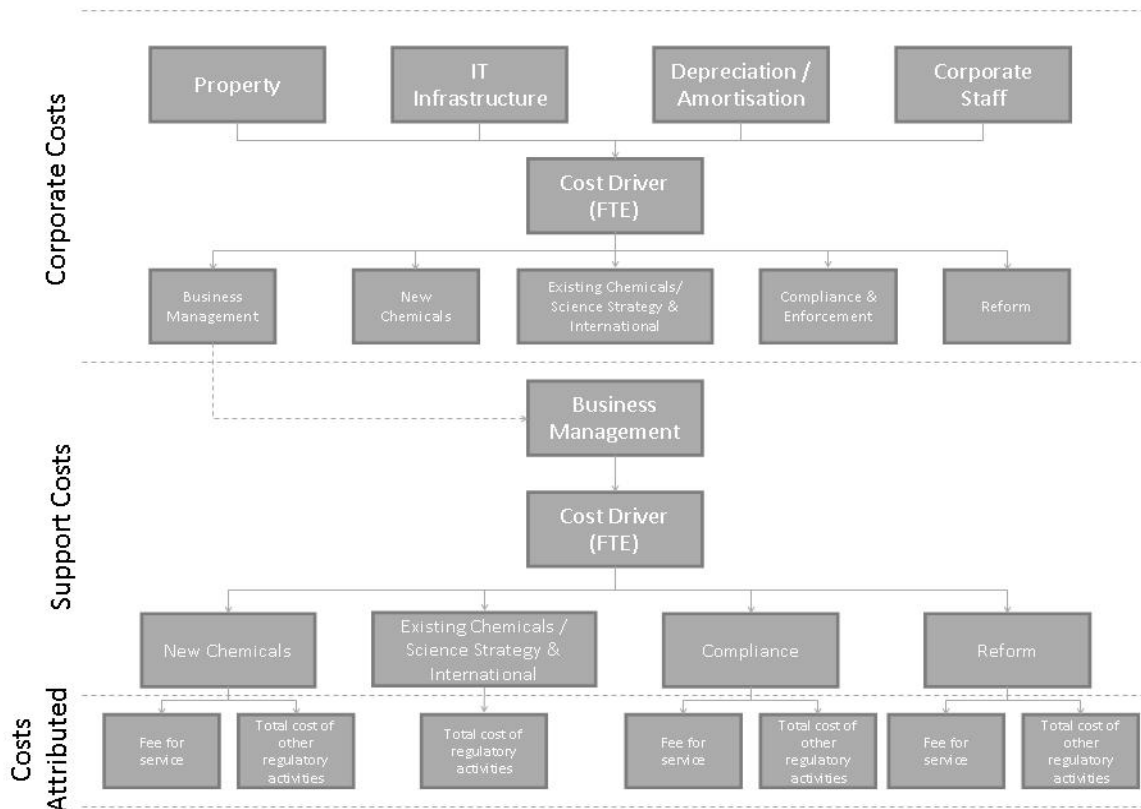
All corporate costs (such as property, IT, finance, communications etc) are required to be disaggregated and spread through the model to provide the full cost of each activity. Corporate costs closely linked to a particular activity were allocated to that activity. Corporate costs not attributable to a particular activity were aggregated and allocated on the basis of full time staff equivalents (FTE) involved in each activity. Given the relatively consistent manner in which most corporate costs are 'consumed' by each team based on staff numbers (e.g. similar IT requirements, similar floor space requirements per staff member etc) there was no requirement to add any further complexity to this attribution process. Business management support costs not closely linked to a particular activity were treated in a similar manner and attributed on the basis of FTE.

Environmental assessment services are outsourced activities undertaken for NICNAS by the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC). Prices charged to NICNAS are set to recover that agency's cost associated with providing their services. This cost is incorporated into the direct cost of individual assessments, where appropriate, or into the total costs of the relevant activity and then attributed in a manner consistent with the other costs of the activity. DSEWPaC costs are reviewed regularly.

Figure 2 summarises the attribution process undertaken to develop the hourly rate per activity as well as the total cost of the regulatory activities.

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**Figure 2 – Attribution Process**



NICNAS maintains a separate cost centre for each of the principal areas of activity which, following the assignment of corporate and support costs, readily permits monitoring of cost recovery activities.

The table below outlines the costs of undertaking the registration process (fee for service) and the activities recovered via the registration charge (levy) during the period of the ABC study, from 1 April 2009 to 31 March 2010. The table also includes the total cost for assessment and AICS fee for service activities.

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**Table 2: Cost Recovery Price – Registration Fee and Other Activities**

Description	Method of recovery	Cost recovery price (period of cost recovery study <sup>3</sup> )
Registration fee (new and annual renewal)	Fee for service	\$642,618
New Chemicals - other than assessment	Levy	\$896,737
Reform	Levy	\$1,059,777
Compliance	Levy	\$867,368
Existing Chemicals / Science Strategy & International	Levy	\$2,796,567
<i>Total Registration Fee and Levy recoverable amount</i>		<b>\$6,263,067</b>
Plus Assessment and AICS Fee for Service Activities	Fee for service	\$2,221,311
		<b>\$8,484,378</b>

Over time, and largely as a result of annual levies not being updated each year for movements in costs, the total revenue received from annual registration fees and charges has not fully recovered these costs. By the period 1 April 2009 to 31 March 2010 the shortfall had grown to approximately \$285,000 (Table 3).

**Table 3 –Revenue Shortfall (During ABC Study Period)**

Post market activities	Actual amount recovered	Calculated cost (period of cost recovery study)	Percentage of costs recovered through fees and charges
Activities funded through annual registration fees and charges	\$5,978,469	\$6,263,067	95%

### 3.3.1 Efficient Costs

Between 2005-06 and 2011-12 the New Chemicals fees and charges have increased with inflation every year except 2011-12 (see Table 4 below). In contrast, NICNAS registration fees and charges have been indexed on three occasions only despite rises in salary costs and other general cost movements. Although this has resulted in a shortfall in registration income as described above, some of these increases in costs were able to be absorbed through implementing efficiencies such as streamlined procedures for processing registration payments, whole of government travel arrangements, and improved financial reporting, budgeting, and IT (see Appendix C for details).

<sup>3</sup> ABC study period – 1 April 2009 to 30 March 2010.

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**Table 4 – Summary of increases in New Chemicals and registration fees and charges since the 2005 CRIS**

Financial Year	Per Cent Increase From Previous Year	Increase Applied to New Chemicals Fees and Charges	Increase Applied to Registration Fees and Charges
2005-06	3.63	Yes	No
2006-07	3.9	Yes	Yes
2007-08	3.83	Yes	Yes
2008-09	3.9	Yes	No
2009-10	4.15	Yes	No
2010-11	3.6	Yes	Yes
2011-12	0	No	No

NICNAS has compared fees payable by introducers of industrial chemicals and notifiers of new chemicals with those payable to other comparable national and international regulators operating on a cost recovery basis and/or cost transparency (Appendix B).

The APVMA, TGA and NICNAS have broadly similar roles in that they all undertake pre-market assessment activities and post-market assessments and compliance activities. The regulatory frameworks (including the scope of assessment) within each agency, however, are different. These framework differences have an impact on the costs of assessment. As a direct comparison, the majority of NICNAS assessment fees are lower than those of the TGA or APVMA. The scope of assessment, however, is usually greater for the TGA and APVMA than NICNAS. While the three agencies have annual levies, these are not directly comparable because the charging regimes are based on features of individual regulatory frameworks. Staffing levels between these agencies are broadly comparable in relation to the size of the business.

International authorities that have functions comparable to NICNAS include the European Chemicals Agency (ECHA), the United States Environmental Protection Agency (US EPA) and Health Canada/Environment Canada. It is difficult to make direct comparisons on costs for the assessment or evaluation of a chemical substance between NICNAS and ECHA due to the substantial differences between the two schemes. The US EPA notification and assessment scheme is similar to NICNAS except that no assessment reports are published, cosmetics are not within scope, a large proportion of assessments do not proceed to completion and only approximately 25 per cent of new substances assessments are cost recovered from industry. Funding for the remaining 75 per cent and its existing chemicals program is provided by government. The Canadian assessment scheme is very similar to NICNAS except that cosmetics are not within the scope of the Canadian scheme and an occupational health and safety risk assessment is not conducted. Cost recovery arrangements are quite different in Canada, however, with approximately 14% of costs recovered from industry for new substances. Accordingly the fees charged to industry in Canada for a new chemicals assessment are lower than NICNAS fees. It is therefore difficult to compare costs between comparable international authorities and NICNAS.

NICNAS maintains assets which are commensurate with the level of services it is required to deliver. Any costs incurred in acquiring relevant assets are treated as a capital expense and depreciated over the estimated useful life of the asset. Estimated future capital expenditure is reported to DoHA through a four year capital management plan which is updated annually. Capital expenditure is generally funded from NICNAS reserves and reviewed by the IGCC. NICNAS receives no funding from Government through the Departmental Capital Budget.

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As noted elsewhere in this CRIS, consultation with industry and government, currently through the IGCC, plays a key role in assisting in the monitoring of NICNAS, providing an important mechanism for ensuring cost control. The IGCC reviews and comments on NICNAS business plans, the annual budget, and fees and charges proposals. The IGCC discusses progress of NICNAS activities at its meetings held at least three times per year.

### ***3.4 Outline of Charging Structure***

As outlined previously, NICNAS has a mixture of fee for service activities, where the charge can be explicitly linked to the provision of the service, and activities funded through a levy, where the direct relationship between activities and a specific organisation or individual is not as clear, but the group of organisations (or individuals) creating the need for regulation is easily definable.

The proposed fees and charges are based on current costs, adjusted to reflect the cost structures anticipated for the period prior to the next review (2015-16). Volumes of activity have been estimated based on current activity levels, adjusted where emerging trends and other influences require the use of an adjusted estimate. Stakeholders have the opportunity to comment on these estimates during consultation on this draft CRIS.

Unlike in the previous fee setting exercise for the NICNAS 2005 CRIS, the ABC study that informs this CRIS did not include the costs of activities such as program related support activities (for example development of risk assessment methodology and staff training) in the calculations of fee for service activities. Rather, a more limited definition was applied, capturing only the direct costs associated with the fee for service activities (including the corresponding overheads). Using this definition, program related support activities will be funded via the annual registration levy.

The proposed fees are based on the removal of any rebates (which currently occur in some New Chemical assessment categories) and thereby represent the actual cost associated with undertaking the relevant activity. This provides industry with surety of costs when they are contemplating an application.

### ***3.5 Summary of Charging Arrangements***

Table 14 summarises the fees proposed for the fee for service activities. These fees are based on the cost of undertaking the current fee for service activities during the period of the ABC study, from 1 April 2009 to 31 March 2010. It is worth noting that the methodology used to calculate the costs in this ABC study apply a different definition of what constitutes time spent on an assessment to that which was used during the previous ABC study that informed the 2005 CRIS (upon which the current fees are based). The previous study included activities such as the training required by assessors in the fees charged for assessments, whereas this study includes only the time spent directly on the assessment. Costs for activities such as assessor training will be recovered through the registration levy.

Where there were no units completed during the period of the ABC study, the cost recovery price was set to be the same as a similar activity. For example, no applications were received during the ABC study period for a Commercial Evaluation (CER) Permit Renewal, however, it was assumed that the effort required to process this type of application should be similar to that for a Low Volume Chemical (LVCR) Permit Renewal application (of which 16 were processed during the period). Therefore, the cost recovery price of the CER permit renewal has been set to be the same as the LVCR application.

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Where no similar activity could be identified it is assumed that the cost recovery price is consistent with the actual fee. For example, no applications were received during the ABC study period to be a Holder of Confidence and no similar activity can be identified. Therefore, the cost recovery price is assumed to be the same as the actual fee.

There were no applications made with an accompanying assessment made by a comparable agency (Modular – STD, Modular - LTD and Modular – PLC categories) during the period of the ABC study, however, some of these applications have been received subsequently. Sub-regulation 15(6) of the IC(NA) Regulations 1990 details that the Director may remit up to 40 per cent of the fee paid for an application under certain circumstances (i.e., application is accompanied by an assessment of the chemical by the TGA, APVMA, FSANZ or by a chemicals notification and assessment scheme operating in a member country of the EU or the OECD). Based on recent experience, the effort involved in undertaking these assessments, however, is estimated to be 20 per cent less than that of an assessment made without submitting an accompanying assessment. It is therefore proposed that the current rebate system is replaced by a fixed fee being approximately 80 per cent of the corresponding certificate assessment category.

Sub-regulation 15(7) of the IC(NA) Regulations 1990 details that the Director may remit up to 40 per cent of the fee paid for an application where it is accompanied by an assessment previously done by NICNAS on a similar chemical. The regulations also allow the Director to remit up to a further 20 per cent of the fee paid if the chemical has a similar use to the previously assessed chemical. There were no applications made under this category during the period of the ABC study. Based on experience, however, the amount of effort involved in undertaking these assessments is estimated to be less than that of a chemical assessed under an approved foreign scheme. It is therefore proposed that the current rebate system is replaced by a fixed fee being approximately 60 per cent of the corresponding certificate assessment category when an application is accompanied by a previous NICNAS assessment on a similar chemical.

For the activities with no units completed, the resulting cost recovery price may or may not be appropriate. NICNAS will review these fee categories if and when the volume increases to allow an analysis of the costs to be undertaken.

Examples of the ABC calculations for Standard certificates and AICS confidential listing are included below.

The processes involved in a New Chemicals Standard assessment are administration (including receipt of application, financial processing of payment, preparation of Gazette notice, filing), assessment (scientific risk assessment encompassing evaluating the chemical identity, the predicted hazard and the extent of exposure/release, and formulating recommendations for safe use), DSEWPaC assessment of environmental risks, and quality assurance (peer review followed by approval to issue the certificate by the Director NICNAS). Officers at different levels undertake various parts of this activity.

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**Table 5 –New Chemicals Standard (STD) Fee Calculation**

Description	Average Hours	Cost recovery price (period of cost recovery study <sup>4</sup> )
Administration	9.3	\$1,058
Assessment – Human health	53.6	\$6,430
Quality assurance	18.7	\$2,711
DSEWPaC – Environmental assessment	n/a <sup>5</sup>	\$4,578
<b>Total Cost</b>		<b>\$14,777</b>

The processes involved in an AICS Confidential Listing are administration and technical (including receipt and checking of application for completeness, financial processing of payment, preparation of briefing for the Technical Advisory Committee (TAG), liaison with the applicant regarding any TAG queries, preparation of briefing for decision by the Director NICNAS, and informing applicant of the decision). The TAG is integral to this process as the Director NICNAS must, under the *IC(NA) Act*, weigh commercial against public interests in coming to a decision on an application for confidential listing. To assist in this process, the Director draws on advice from the TAG, with expertise in chemistry and the human and environmental toxicology of industrial chemicals. Officers at different levels undertake various parts of this activity.

**Table 6 –AICS Confidential Listing Fee Calculation**

Description	Average Hours	Cost recovery price (period of cost recovery study)
Administration / Technical	20.7	\$2,359
Technical Advisory Committee (TAG)	n/a	\$784
<b>Total Cost</b>		<b>\$3,143</b>

<sup>4</sup> ABC study period – 1 April 2009 to 30 March 2010. Hourly rates include overheads as described in section 3.3.

<sup>5</sup> DSEWPaC prices are set to recover that agency's cost associated with providing their services.

## 4 PROPOSED CHANGES TO THE COST RECOVERY ARRANGEMENTS

### 4.1 New fees

In addition to the current fee for service activities undertaken by NICNAS a number of other activities are proposed to be cost recovered through a fee for service arrangement, rather than funded from the registration levy. This is consistent with the Cost Recovery Guidelines in that it is desirable, where possible, to charge for activities directly through fees. It is also proposed to remove the current rebates for some New Chemicals assessment products (e.g., Modular – Secondary Chemical) and replace with set fees.

The cost recovery fees which would have applied for these activities during the period of the ABC study (had a fee been in place) are presented in the table below, along with actual volume and the total cost recovery revenue that would have been collected over the period of study. A discussion regarding the proposed activities follows.

**Table 7: Estimated Fees for proposed fee for service activities, 1 April 2009-30 March 2010**

Description	Method of recovery	Cost recovery price (period of cost recovery study)	Units (period of cost recovery study)	Total cost recovery revenue (period of cost recovery study)
Group Assessment – STD (was Modular - Secondary Chemical)	Fee for service	\$3,571	1	\$3,571
Group Assessment – LTD or PLC (was Modular - Secondary Chemical)	Fee for service	\$2,143	1	\$2,143
PIC - Category A	Fee for service	\$666	67	\$44,622
PIC - Category B	Fee for service	\$1,316	10	\$13,160
				<b>\$63,496</b>

#### 4.1.1 Group Assessment (was Modular – Secondary Chemical assessment)

The Group Assessment (previously known as Modular – Secondary Chemical) fee is applicable if a second chemical is being notified at the same time as a similar primary chemical and for a similar use. The process NICNAS needs to undertake for a modular assessment is:

- screen the chemical, check its identity and confirm that it is a similar chemical to the primary chemical, including consideration of toxicity profiles where required;
- incorporate information on the secondary chemical in the assessment report for the primary chemical (i.e., produce one report for all chemicals in the assessment); and
- issue the certificate.

Sub-regulation 15(8) of the IC(NA) Regulations 1990 details that the Director may remit part of the fee paid for an application made at the same time as another application. This means that currently

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when a group assessment application is made, the notifier must pay the appropriate fee for the primary chemical (e.g., a standard certificate fee) and the same amount for any secondary chemicals. After the assessment is completed, NICNAS rebates some of the applicable fee for the secondary chemicals. Current practice is to rebate approximately 80% of the applicable fee, calculated on a case-by-case basis, based on the amount of effort required to complete the secondary chemical assessment. The ABC study, however, identified that there was a different effort required for a secondary STD chemical versus a secondary LTD chemical. It is therefore proposed that the current rebate system be replaced by the above assessment fees.

There were no applications for a group assessment - PLC during the ABC study period. Although the primary assessment of a LTD and PLC have different fees reflecting the different level of effort involved undertaking the assessment, it has been estimated that the effort for assessing a secondary chemical of a LTD or PLC would be very similar. Thus, the fee for a group assessment – PLC has been set the same as a group assessment – LTD.

### 4.1.2 Prior Informed Consent authorisation

The Rotterdam Convention (which Australia has ratified) places obligations on the importer and exporter of certain hazardous chemicals. Under the Rotterdam Convention countries nominate chemicals which have been severely restricted or banned in their country and once approved for inclusion in the Prior Informed Consent (PIC) procedure these chemicals will be subject to controls in international trade. Under these controls organisations wishing to import or export listed chemicals must first seek authorisation from NICNAS (Section 106 of the *IC(NA) Act* and Regulation 11C of the *IC(NA) Regulations 1990*). As this is a distinct activity instigated by the relevant organisation and able to be costed as a discrete application process, cost recovery via a fee for service is appropriate.

The ABC study found that the resources required in providing an authorisation vary depending on the destination of the proposed export. Therefore, for the purposes of cost recovery, PIC authorisation can be further classified into two groups. Category A representing exports to countries whose status regarding the Rotterdam Convention is unambiguous and Category B which includes any country where additional resources will be required to determine the destination country's acceptance of the proposed exported chemicals.

There were no PIC annual authorisation applications for the importation of chemicals during the period of the ABC study. Based on applications received since the study, however, it is estimated that the amount of effort is similar to that of Category B as there are a number of follow up processes such as audits to check the use of the chemical was as stated in the application.

### 4.1.3 Screening fees

NICNAS proposes to introduce a non-refundable screening fee for all New Chemical applications. The proposed screening fee is 15 per cent of the value of each assessment fee (based on the screening effort calculated through the ABC study). The screening fee would be a component of the overall assessment fee. For example the non-refundable screening fee component of the STD assessment fee in 2012-13 (see Table 14, Section 6) would be \$2,520 (15 per cent of \$16,800), with the remaining \$14,280 returned if the application was rejected as described below.

NICNAS will undertake a preliminary assessment (screening) of an application to assess whether the application meets all the requirements as prescribed by the legislation. If all the requirements are met

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NICNAS will inform the notifier that the application has passed the preliminary assessment and that a full evaluation of the information submitted will proceed.

If the preliminary assessment determines that there are deficiencies in the application but that these deficiencies can reasonably be rectified NICNAS will inform the notifier of these deficiencies and agree a timeframe in which the applicant is to rectify the deficiencies. If the deficiencies are not addressed within the agreed timeframe NICNAS may defer consideration of the application or treat the application as having been withdrawn and will inform the notifier of its decision.

If the preliminary assessment determines that there are deficiencies in the application which cannot reasonably be rectified NICNAS may reject the application. If NICNAS rejects the application it will inform the notifier giving reasons for its decision. The screening fee will be retained by NICNAS; however monies in excess of the screening fee will be repaid. Any subsequent assessment application will require a new application fee (including a screening fee).

Introduction of a non-refundable screening fee for screening of New Chemical assessment applications will discourage notifications that do not contain required supporting data.

### ***4.2 Removal of fees for service***

#### **4.2.1 Transfer to a Confidential Listing**

It is proposed to remove Transfer to a Confidential Listing from the fee schedule as this option was only available during the transition period in 1997 and as such is no longer a relevant category.

#### **4.2.2 Template rebate**

Currently a discount is provided if an assessment is received by NICNAS via the electronic template. Through the ABC study it became clear that the electronic templates do not necessarily result in a reduction in effort. In fact, some assessments received via the electronic template took longer to complete compared to situations where the information was provided to NICNAS separately. As a result the set fees in table 14 represent the average cost of undertaking each assessment whether lodged via an electronic template or not. Therefore, these fees remove the discount provided for assessments submitted via the electronic template.

### ***4.3 Change to annual registration fee***

All commercial introducers of industrial chemicals are required to register with NICNAS for each year in which they import or manufacture industrial chemicals and be placed on the Register of Industrial Chemical Introducers as set in Part 3A of the *IC(NA) Act*. The process of registration is covered with a registration fee set to cover the administrative cost of establishing and maintaining the registration. The annual registration fee for 2011-12 is \$395.

As part of the ABC study, the administration costs were recalculated, resulting in a revised figure of \$112 per introducer as the cost recovered price for the period of the ABC study. This reduction in administration costs is likely to be as a result of efficiencies achieved within NICNAS (including economies of scale) as well as a more narrow definition with only the time spent on the administration

tasks directly related to the annual registration process being costed in this study (in a similar manner to the pre-market assessment activities).

#### 4.4 Change to annual levy structure

In addition to the fee for service activities, a registration charge (a levy) is imposed on commercial introducers of industrial chemicals with an annual value of introduced industrial chemicals in excess of \$500,000. Registration charges are used to recover regulatory costs relating to the compliance program, stakeholder information and education, existing chemical reviews and scheme support activities (including international harmonisation). These costs are not related to the provision of a specific service to an introducer, but provide identifiable benefits to the industry.

Registration fees and charges are payable at the time of first entry onto the register of chemical introducers, with renewals falling due on or before 31 August each year. The *IC(NA) Act* specifies circumstances under which the Director may refund registration charges where an introducer registers at a particular tier, but subsequently introduces less than the threshold value of chemicals for that tier.

NICNAS registration is not intended to add unduly to industry accounting or record keeping requirements. The value of relevant industrial chemicals is calculated on a formula given in subsection 7A(2) of the *IC(NA) Act*. Industry can base their registration on reasonably justifiable estimates. Relevant commercial documents such as commercial invoices, order/confirmation, bills of lading/airway bills, insurance certificates or receipts for purchase of goods may be used. It is recommended, however, that a record is kept on how the calculations were made. Registrations are subject to random audits and it is an offence to provide misleading information. All relevant commercial documents relating to industrial chemicals imported into Australia must be kept for at least five years.

A higher registration charge is attributable to companies with larger industrial chemical introduction value. Large introducers create a greater need for regulation than small introducers. The greater value of industrial chemicals introduced generally reflects a larger volume of industrial chemicals introduced. A larger volume means greater potential exposure and therefore potentially greater risk to workers, the public and the environment from the harmful effects of industrial chemicals. This assumption will be monitored, and amendments to the charging structure may be made in the future where evidence based.

The total charge (including registration fee) payable for 2011-12 is summarised in the table below.

**Table 8 – 2011-12 Registration Fee and Charge (Levy)**

Tier	Applicable introduction value <sup>6</sup>	Registration Fee & Charge	Approximate number of companies	Cost as per cent of minimum introduction value <sup>7</sup>
1	\$1 - \$499,999	\$395	3,470	n/a
2	\$500,000 - \$4,999,999	\$1,577	940	0.32%
3	\$5,000,000 or more	\$9,201	380	0.18%

<sup>6</sup> Value of relevant industrial chemicals imported or manufactured each year

<sup>7</sup> Calculated by dividing the registration fee and charge by the minimum applicable introduction value for that tier. E.g., for tier 2,  $1577 \div 500000 = 0.32\%$ .

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Currently, the larger the organisation, the proportionally (as a percentage of introduction value) less it pays to register. For example:

- 4 companies introduce more than \$2 billion each (with current annual charges at tier-3 equating to less than 0.00046 per cent of introduction value);
- 21 companies introduce and/or manufacture between \$100 million and \$2 billion each (with current annual charges at tier-3 equating to between 0.0092 and 0.00046 per cent of introduction value); and
- 94 companies are paying greater than 100 percent of the value of chemicals introduced in registration fee to NICNAS (that is introducing less than \$395 worth of relevant industrial chemicals per year).

### 4.4.1 Annual registration fee and charges for 2012-13 to 2015-16

A number of alternative annual charging regimes were analysed. While the number of alternatives is theoretically infinite, there are a number of key principles outlined in the Cost Recovery Guidelines that must be adhered to; for example it should not be very costly or complex to collect and it should not create incentives to avoid registration (and therefore increase the costs of enforcement and reduce the usefulness of the register). Full details of the options analysed can be found at Appendix D.

The preferred option involved creating four tiers, splitting the current tier-1 into two. This model results from the reduced cost of the administrative aspects of the annual registration process, coupled with the desire to increase the number of introducers making a contribution to post market activities.

The preferred model will result in the following changes:

- Ensures the direct costs associated with the annual registration process are covered by the annual registration fee;
- More than 4,000 of the introducers will pay less than the amount they are currently paying while less than 370 introducers will pay more (see table 9); and
- Reduces the number of registrants paying more than 100% of the introduction value from 94 to 42.

It is proposed to transition to a four tiered annual fee structure from 2013-14, given the timing for legislative amendments required to implement such a structure. Therefore, NICNAS will retain the current 3-tiered registration structure in 2012-13, although slightly amended, and will carry an approximate \$200,000 shortfall in registration income in that year, which will be absorbed by NICNAS. This equates to the following fee structure:

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**Table 9 – 2012-13 Registration Fee and Charge**

Tier	Applicable introduction value	Current registration fee and charge (2011-12)	Proposed registration fee and charge (2012-13)	Per cent change	Approximate number of companies	Cost as a percent of minimum introduction value <sup>8</sup>	Total amount recovered
1	\$1 - \$499,999	\$395	\$295	-25%	3,470	n/a	\$1,023,650
2	\$500,000 - \$4,999,999	\$1,577	\$1,577	0%	940	0.32%	\$1,482,380
3	\$5,000,000+	\$9,201	\$11,500	+25%	380	0.23%	\$4,370,000
							<b>\$6,876,030</b>

Moving to the four tier structure in 2013-14 and removing the shortfall in income from the registration levy will result in the fee structure shown in Table 10. This fee structure was developed to remove the inequity in charging across the tiers. Working within the framework of the total amount needed to be recovered, the number of tiers and the fee for tier-1 matching the administration fee (as calculated during the ABC study and indexed for inflation and wage cost increases), results in the registration fee and charge equating to 0.29 per cent of the minimum introduction value for all tiers, except for tier 1.

**Table 10 – 2013-14 Registration Fee and Charge**

Tier	Applicable Introduction Value	2013-14 Proposed Registration Fee and Charge	Approximate Number of Companies	Cost as per cent of minimum introduction value	Total amount recovered
1	\$1 - \$99,999	\$133	2,720	n/a	\$361,760
2	\$100,000 - \$499,999	\$295	750	0.29%	\$221,250
3	\$500,000 - \$4,999,999	\$1,430	940	0.29%	\$1,344,200
4	\$5,000,000+	\$14,300	380	0.29%	\$5,434,000
					<b>\$7,361,210</b>

<sup>8</sup> Calculated by dividing the registration fee and charge by the minimum applicable introduction value for that tier. E.g., for tier 2,  $1577 \div 500000 = 0.32\%$ .

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The table below summarises the NICNAS Registration fees and charges for the period 2012-13 to 2015-16 based on an estimated indexation rate as outlined in section 4.6.

**Table 11 – Summary of proposed NICNAS Registration Fees and Charges from 2012-13 to 2015-16**

Tier	Applicable introduction value	2011-12 current fee and charge (\$)	2012-13 proposed fee and charge (\$)	2013-14 proposed fee and charge (\$)	2014-15 proposed fee and charge (\$)	2015-16 proposed fee and charge (\$)
1	\$1 - \$99,999	395	295	133	138	143
2	\$100,000 - \$499,999	395	295	295	305	315
3	\$500,000 - \$4,999,999	1,577	1,577	1,430	1,480	1,535
4	\$5,000,000+	9,201	11,500	14,300	14,800	15,350
<b>Total amount recovered</b>		<b>\$6,349,410</b>	<b>\$6,876,030</b>	<b>\$7,361,210</b>	<b>\$7,619,310</b>	<b>\$7,901,110</b>

### 4.5 Late payment penalty fees

Fines and pecuniary penalties are not cost recovery for the purposes of the cost recovery policy. A discussion on the late penalty fee is being included here for completeness.

Under sections 80KB and 110A of the *IC(NA) Act* late registration renewal applications are subject to a penalty. The amount of the penalty is prescribed in Regulation 18 of the *IC(NA) Regulations 1990*. The current penalty is 15% of the sum of registration fee and any applicable registration charge.

During the ABC study it was found that if a payment for an annual levy amount is late the cost for NICNAS to confirm late payment, send correspondence to the relevant party and process the payment was \$80. This is a reasonable deterrence for the tier-1 introducers to pay on time, but for some of the higher tiers it is not.

NICNAS proposes using a penalty fee in 2012-13 of \$100 or 10% of the sum of the registration fee and any applicable charge, whichever is the greater, rounded to the nearest \$5. This would offset costs and act as a reasonable deterrent for introducers to avoid being late with their payment. A summary of the applicable late penalty fees for 2012-13 to 2015-16 is included in section 6.

NICNAS proposes to use any revenue received from late penalty payments, above the cost to NICNAS to process these payments, to increase the NICNAS reserve (see section 4.7).

### 4.6 Annual updates to fees and charges

As part of the 2004-05 budget setting process, the IGCC agreed to use an indexation model to adjust fees and charges in line with cost and wage movements in the public sector. The index model used was comprised of 75 percent of the Wage Price Index (WPI), reflecting average wage movements, and 25 percent of the Consumer Price Index (CPI). It was also agreed, that this adjustment would not be automatic, but would be considered in full consultation with the IGCC together with any additional regulatory cost pressures. This approach was expected to encourage regulatory efficiency and enhance the predictability of fees for industry. This model has continued to be used for any fee and charge increases.

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One of NICNAS's largest costs is wages. Employee costs equate to approximately 64 per cent of the total operating costs of NICNAS. When the cost of services provided by DSEWPac (in completing the environmental aspects of relevant new chemicals assessments) are added to this figure (as they are effectively driven by employee costs) this figure increases to approximately 70 per cent. As a result it appears the current blend of a wage based index and a broader inflation measure is appropriate. Indexing the fees and charges by CPI alone, or a 50:50 mix of CPI and WPI would not recover cost increases in a manner consistent with the way in which they grow.

Currently annual fees and charges are not automatically updated for inflation as automatic indexation is not consistent with the cost recovery policy. However, NICNAS is seeking stakeholders' views on the proposed indexation of fees and charges for the duration of this CRIS (2012-13 to 2015-16) as outlined in section 6 to allow better predictability of available resource levels for NICNAS in order to plan projects that run over multiple years. NICNAS will monitor actual costs to ensure that indexation rates are reflective of cost change rates.

### ***4.7 Level of Reserve***

The NICNAS budget is based on predicted levels of new chemicals notifications and the numbers of expected registrants in each tier. In making these estimates NICNAS is guided by activity levels in preceding years and advice from the IGCC on anticipated industry activity. Fluctuations in industry activity potentially impact NICNAS in two ways to result in lower (or higher) than expected revenue:

- lower (or higher) than budgeted numbers of new chemicals applications; and/or
- lower (or higher) than budgeted number of companies maintaining NICNAS registrations.

A reserve is used as a risk mitigation strategy by cost recovered agencies to allow them to continue business in the event that there is a shortfall in income and to prevent the need to go back through the budget process to make up the deficit. NICNAS currently holds a contingency fund of ten per cent of the annual cost of NICNAS (equivalent to a little over one month's operating expenses) in reserves agreed to by the IGCC. Other comparable agencies hold a reserve equal to three months operating expenses. NICNAS would need to grow the current reserve by approximately \$1.5 million to reach an equivalence of three months operating expenses.

Given the extent of fluctuations in levels of activity experienced in recent years, NICNAS proposes to increase the reserve (by the amount of the interest equivalency payment currently received each year and any late penalty payments above the cost of processing these penalties) until it reaches 3 months operating expenses. Once the desired level of reserve is reached, the interest equivalency payment may be used to fund capital purchases or other NICNAS activities, which may result in a reduction in future levy increases. Industry is not being asked to contribute to increase the reserve.

It is also worth noting that in this context the level of the reserve refers to the level of funding available for NICNAS to draw down from for operational purposes. It therefore excludes funding required to be held for such purposes as employee provisions (and to that extent the total balance at any point in time should exceed three months operating expenses). Furthermore, given the uneven nature of NICNAS revenue (owing to introducers being required to pay the registration fee and the annual levy at the beginning of the registration year) assessing the level of NICNAS's cash balance at a particular point in the year may be misleading.

## **5 PROPOSED CHANGES TO RECOVER THE COST OF THE ACCELERATED ASSESSMENT AND PRIORITISATION OF EXISTING CHEMICALS**

### **5.1 Background**

The Australian Inventory of Chemical Substances (AICS) was established for the purposes of implementing the *ICNA Act*. It includes those chemical substances that were reported by industry to be in use in Australia between 1977 and 1990 and therefore “existing” in commerce. It also contains new chemicals subsequently assessed. The AICS is the legal device that distinguishes new from existing chemicals, and industrial chemicals listed on AICS are considered existing chemicals.

Of the approximately 39,000 chemicals currently on AICS, approximately 38,000 were nominated by industry (“grandfathered” as existing chemicals) in 1990 and the vast majority have not been assessed for their effects on human health and the environment, either by NICNAS or internationally. Relatively few of these existing chemicals (approximately 200 of 38,000) have been subsequently assessed by NICNAS, under the current Existing Chemicals Program.

The Productivity Commission Chemicals and Plastics Regulation, Research Report (2008) recommended that NICNAS should implement a program to greatly accelerate the assessment of existing chemicals and that the Australian Government should meet the cost of screening all existing chemicals from budget funding. In November 2008, COAG noted the response of the Commonwealth as set out below.

*The Productivity Commission’s recommendation envisages a resource intensive, Government-funded approach to assessment of existing chemicals. The extent and speed of implementation of this recommendation would be dependent on available funding. The recommendation for budget funding of this activity is not consistent with current cost-recovery policy as implemented in the National Industrial Chemicals Notification and Assessment Scheme. Resource implications require consideration in the development of an implementation plan.*

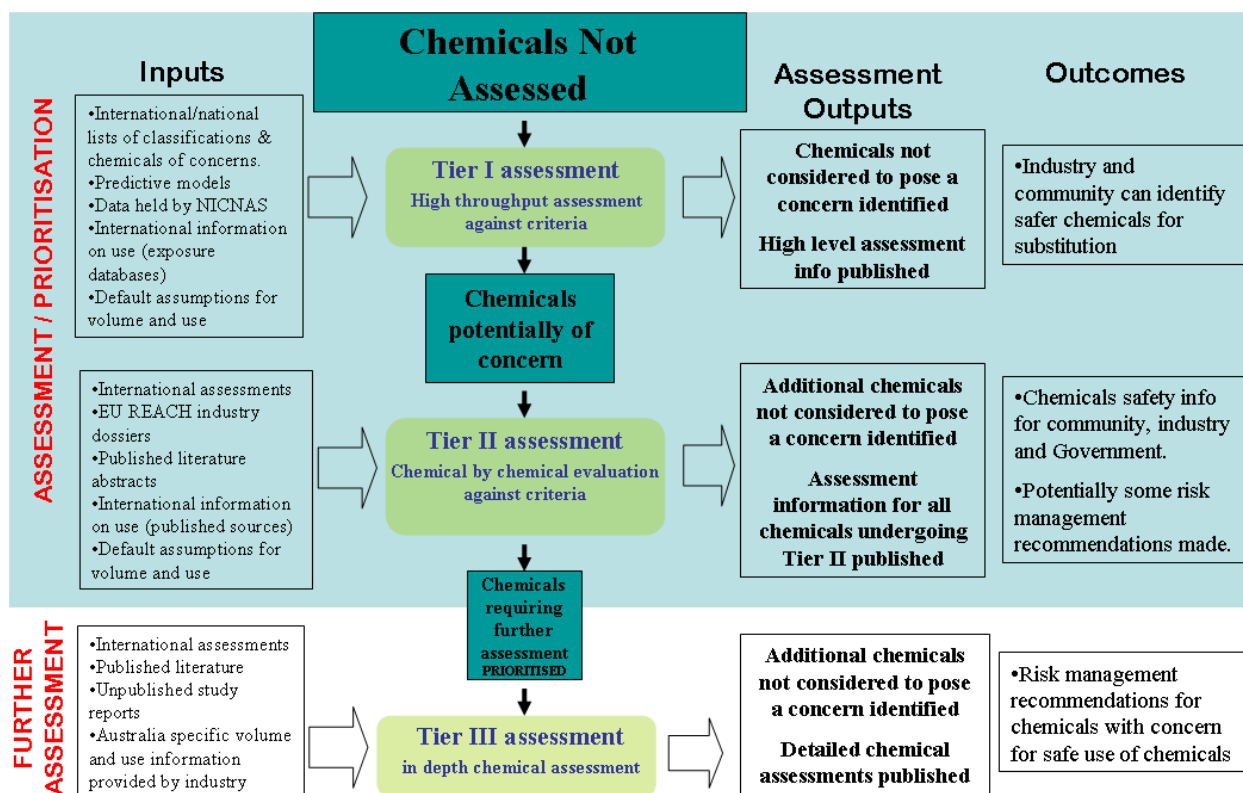
A staged approach will be used to implement the assessment and prioritisation framework, with the progression and evaluation of stage one over a four year timeframe.

### **5.2 Analysis of Activities**

#### **5.2.1 Description**

NICNAS has developed a tiered risk based (using information about the hazardous properties of the chemical as well as the nature and extent of the usage) framework for the assessment and prioritisation of chemicals on AICS in consultation with key stakeholders (Figure 3). The framework uses information generated overseas where applicable, predictive modelling and other available data. Industry will not be required to provide information on the use of chemicals in Australia during the first two tiers of the framework, although NICNAS would welcome any relevant information that is provided voluntarily.

Figure 3 – Framework for the Assessment and Prioritisation of Existing Chemicals



A staged approach will be used to implement the assessment and prioritisation of chemicals on the AICS. Stage one will focus on a subset of chemicals on the AICS that stakeholders advised should be considered early in the project. It is envisaged that this stage will comprise the first two tiers of the framework (Figure 3), address approximately 3000 chemicals, and will include an external review to inform the most appropriate process for addressing the remainder of the chemicals on AICS. Stage one will take four years to complete from 2012-13 to 2015-16.

### 5.2.2 Policy Review

The accelerated assessment and prioritisation of Existing Chemicals is an extension of the post-market regulatory activity - Assessment of Existing Chemicals (see Section 2.3.1.1). As with the discussion previously regarding cost recovery of post-market regulatory activities (see Section 2.3.1.2), cost recovery of the accelerated assessment and prioritisation of Existing Chemicals is consistent with policy goals. Charging via the annual registration levy would be efficient and cost effective as it is administratively simple to collect.

### 5.2.3 Conclusion

The accelerated assessment and prioritisation of Existing Chemicals potentially benefits all industrial chemical introducers, end users and the general public by ensuring the safe use of industrial chemicals

through making risk assessment and safety information on chemicals widely available. Also, risk management recommendations will be made to standard setting bodies where appropriate.

Cost recovery of this activity is appropriate because introducers create the need for the activity by having an industrial chemical in the marketplace.

### **5.3 Design and Implementation**

#### **5.3.1 Basis of Charging – Fee or Levy**

As outlined in the Cost Recovery Guidelines, fee for service is the preferred charging basis for the recovery of costs. When assessing the applicability of a fee for service arrangement, the fundamental principle underpinning the cost recovery guidelines is that the costs of the activity need to be able to be directly attributable to an individual organisation (as the instigator of such costs). Fee for service charges also need to be efficient and cost effective. A fee will not be efficient and cost effective if it is difficult to establish a fee that accurately links the costs of the activities to the regulated firms or individuals; or the fee is costly to collect because it is difficult to identify and bill each regulated firm or individual. In considering the basis of charging of the accelerated assessment and prioritisation of Existing Chemicals, there are a number of aspects that restrict the ability to charge on a fee for service basis:

- NICNAS does not hold information on what chemicals are currently being manufactured in or imported into Australia and by which companies, the ability to directly charge companies in absence of this information is severely restricted.
- Charging those organisations that currently manufacture/import the Existing Chemicals on a fee for service basis, without giving them any inherent benefit (over other organisations that can subsequently manufacture and/or import the same chemical) may result in free rider effects.

As a result of the above, it does not appear that a fee for service arrangement for the acceleration of the assessment and prioritisation of Existing Chemicals would be efficient and cost effective. As such, it is proposed that the costs associated with the accelerated program be recovered through the annual registration levy. This is also consistent with the over-arching principle that pre-market assessment is typically better suited to fee for service, while post-market monitoring is typically better suited to a levy.

#### **5.3.2 Legal Requirement for the Imposition of Charges**

As discussed in Section 3.2, legal authority for the annual levy (registration charge), which is considered a tax, is included in the *Industrial Chemicals (Registration Charges – General) Act 1997*. Section 80S of the *IC(NA) Act* provides for the imposition of a registration charge for excise, customs or taxation purposes. Section 3 of the *Industrial Chemicals (Registration Charges – General) Act 1997* provides for the imposition of the registration charge as a levy. The amount of the registration charge is based on tiers prescribed in Section 80T of the *IC(NA) Act* and is based on the value of industrial chemicals introduced, with the level of charge payable included in Regulation 11AB.

### 5.3.3 Costs to be Included in Charges

Based on the proposed framework, the amount required to be recovered to undertake stage one of the accelerated assessment and prioritisation of Existing Chemicals is as detailed in the table below. This is the cost of the additional NICNAS resources required and excludes a proportion of existing NICNAS resources that will be used.

At each successive tier of the assessment framework, the comprehensiveness (and resource intensiveness) of the assessments increase. The increase in costs over the period reflects the increased resources required to undertake the more comprehensive human health and environmental assessments. The increase in cost for governance and stakeholder engagement in 2015-16 is mainly due to the external review and anticipated increase in publications.

**Table 12 – Summary of NICNAS Costs to Undertake Stage One of the Accelerated Assessment and Prioritisation of Existing Chemicals**

	2012-13	2013-14	2014-15	2015-16
Staff <sup>9</sup>	\$1,395,384	\$1,701,468	\$1,996,837	\$1,971,905
Capital (IT and office fitout)	\$88,269	\$20,000	\$20,000	\$20,000
Suppliers (eg.QSAR tools <sup>10</sup> , DSEWPaC, Consultancy, legal, library)	\$141,282	\$328,997	\$435,346	\$218,356
Governance (including review) and Stakeholder engagement communication/publications	\$20,034	\$20,034	\$17,534	\$211,034
<i>Total</i>	<b>\$1,644,969</b>	<b>\$2,070,499</b>	<b>\$2,469,717</b>	<b>\$2,421,295</b>

### 5.4 Outline of Charging Structure

Various options regarding the charging arrangement were considered. These included:

- charging each of the approximately 4,800 registrants the same fee;
- charging each introducer a consistent percentage of the value of chemicals introduced or manufactured; and
- having a tiered approach similar to the current annual registration charge structure.

As with the discussion in section 4.4.1 regarding the annual registration levy framework, many of the principles to provide the most equitable framework remain the same. It is therefore proposed to use the same tiered approach as the registration charge to recover the costs of the accelerated assessment and prioritisation of Existing Chemicals.

<sup>9</sup> Includes overheads as described in section 3.3

<sup>10</sup> Quantitative Structure Activity Relationship (QSAR) tools are predictive computational models which, when applied appropriately, represent valuable tools to help fill gaps in available data on a number of human health and environmental hazard indicators.

### 5.5 Summary of Charging Arrangements

While it is proposed to transition to a four tiered annual fee structure, given the legislative timings required to implement such a structure, it is proposed that in 2012-13 NICNAS will retain the current 3-tiered registration structure.

To minimise the impact on small business, companies introducing less than \$100,000 in relevant industrial chemicals will only contribute \$100 in 2012-13 and make no further contribution to the program in subsequent years.

A summary of the charges applicable to recover the costs of stage one of the accelerated assessment and prioritisation of Existing Chemicals is included below.

**Table 13 – Summary of NICNAS Registration Charges from 2012-13 to 2015-16 to Recover the Costs of Stage One of the Accelerated Assessment and Prioritisation of Existing Chemicals**

Tier	Applicable Introduction Value	Approx. Number of Companies	2011-12 Current Fee & Charge	2012-13 Proposed Fee & Charge	2013-14 Proposed Fee & Charge	2014-15 Proposed Fee & Charge	2015-16 Proposed Fee & Charge
1	\$1 - \$99,999	2,720	n/a	\$100	-	-	-
2	\$100,000 - \$499,999	750	n/a		\$100	\$100	\$100
3	\$500,000 - \$4,999,999	940	n/a	\$280	\$427	\$500	\$500
4	\$5,000,000+	380	n/a	\$2,800	\$4,175	\$5,000	\$5,000
<b>Total amount recovered</b>			<b>n/a</b>	<b>\$1,674,200</b>	<b>\$2,062,880</b>	<b>\$2,445,000</b>	<b>\$2,445,000</b>

## NICNAS Cost Recovery Impact Statement

### 6 SUMMARY OF FEES AND CHARGES

The table below provides a summary of the projected changes to NICNAS fees based on an estimated indexation rate. In applying the indexation rate, fees have been rounded to the nearest \$50 (for amounts up to \$1,000) and the nearest \$100 (for amounts of \$1,000 or more).

**Table 14 – Summary of NICNAS’s Fees from 2012-13 to 2015-16**

	Method of Recovery	2012-13 proposed fee (\$)	2013-14 proposed fee (\$)	2014-15 proposed fee (\$)	2015-16 proposed fee (\$)
<b>Certificate Applications</b>					
Standard Assessment	Fee for service	16,800	17,400	18,000	18,600
Limited Assessment	Fee for service	12,000	12,400	12,800	13,300
Polymer of Low Concern	Fee for service	5,600	5,800	6,000	6,200
Application for Extension of Assessment Certificate	Fee for service	5,100	5,300	5,500	5,700
<b>Self-assessment Certificate Application</b>					
Self-Assessment Application Non-hazardous chemical	Fee for service	10,400	10,800	11,200	11,600
Self-Assessment Application Non-hazardous polymer	Fee for service	9,700	10,000	10,400	10,800
Polymer of Low Concern (SAPLC) Self-Assessment Application	Fee for service	3,900	4,000	4,100	4,200
<b>Permit Applications</b>					
Commercial Evaluation (CEC) Permit Application	Fee for service	4,000	4,100	4,200	4,400
Low Volume Chemical (LVC) Permit Application	Fee for service	4,000	4,100	4,200	4,400
Controlled Use Permit Application (Export Only)	Fee for service	4,000	4,100	4,200	4,400
Controlled Use Permit Application (Other)	Fee for service	4,000	4,100	4,200	4,400
Application for Early Introduction Permit (EIP)	Fee for service	2,300	2,400	2,500	2,600
Section 30 Permit Application	Fee for service	8,500	8,800	9,100	9,400
<b>Permit Renewal Applications</b>					
Commercial Evaluation (CER) Renewal Application	Fee for service	2,000	2,100	2,200	2,300

NICNAS COST RECOVERY IMPACT STATEMENT

	Method of Recovery	2012-13 proposed fee (\$)	2013-14 proposed fee (\$)	2014-15 proposed fee (\$)	2015-16 proposed fee (\$)
Low Volume Chemical (LVCR) Permit Renewal Application	Fee for service	2,000	2,100	2,200	2,300
Controlled Use Permit Renewal Application	Fee for service	2,000	2,100	2,200	2,300
<b>Other Applications</b>					
Secondary notifications of new chemicals, other than a synthetic PLC	Fee for service	9,600	9,900	10,300	10,700
Secondary notifications of a new chemical that is a synthetic PLC	Fee for service	4,200	4,400	4,600	4,800
Alternate State Law Application	Fee for service	10,400	10,800	11,200	11,600
<b>Reduced Fee Options</b>					
Approved Foreign Scheme - STD	Fee for service	12,300	12,700	13,200	13,700
Approved Foreign Scheme - LTD	Fee for service	9,000	9,300	9,600	9,900
Approved Foreign Scheme - PLC	Fee for service	3,500	3,600	3,700	3,800
Assessed by comparable agency – STD (was Modular – STD)	Fee for service	13,400	13,900	14,400	14,900
Assessed by comparable agency – LTD (was Modular – LTD)	Fee for service	9,600	9,900	10,300	10,600
Assessed by comparable agency – PLC (was Modular – PLC)	Fee for service	4,500	4,700	4,900	5,000
NICNAS previously assessed similar chemical – STD (was Modular – STD)	Fee for service	10,100	10,500	10,900	11,300
NICNAS previously assessed similar chemical – LTD (was Modular – LTD)	Fee for service	7,200	7,500	7,800	8,100
NICNAS previously assessed similar chemical – PLC (was Modular – PLC)	Fee for service	3,400	3,500	3,600	3,700
Group Assessment – STD (was Modular - Secondary Chemical)	Fee for service	4,000	4,100	4,200	4,400
Group Assessment – LTD or PLC (was Modular - Secondary Chemical)	Fee for service	2,500	2,600	2,700	2,800
<b>New Chemicals Assessments</b>					
Variation of Schedule Data Requirements	Fee for service	2,600	2,700	2,800	2,900
Nomination of Foreign Scheme	Fee for service	7,100	7,400	7,700	8,000
Exempt Information	Fee for service	1,100	1,100	1,100	1,100
Application to Vary Assessment Report	Fee for service	4,100	4,200	4,400	4,600
Application to Vary Full Public Report	Fee for service	4,100	4,200	4,400	4,600
<b>AICS</b>					
Confidential Listing of a New Industrial Chemical	Fee for service	3,500	3,600	3,700	3,800

NICNAS COST RECOVERY IMPACT STATEMENT

	Method of Recovery	2012-13 proposed fee (\$)	2013-14 proposed fee (\$)	2014-15 proposed fee (\$)	2015-16 proposed fee (\$)
Application to Retain Confidential Listing	Fee for service	3,500	3,600	3,700	3,800
Application for Early Non-confidential Listing with fee	Fee for service	750	800	800	850
Application to be a Holder of a Confidence	Fee for service	700	700	750	800
Transfer to Confidential listing	Fee for service	2,100	n/a	n/a	n/a
<b>Prior Informed Consent</b>					
PIC – Export Category A	Fee for service	n/a	750	800	850
PIC – Export Category B	Fee for service	n/a	1,700	1,800	1,900
PIC – Import	Fee for service	n/a	1,700	1,800	1,900

## NICNAS Cost Recovery Impact Statement

The table below provides a summary of the combined registration fee and charges to cover the costs associated with ongoing activities (table 9) and stage one of the accelerated assessment and prioritisation of existing chemicals (table 13).

**Table 15 – Summary of NICNAS’s Registration Fee and Charges from 2012-13 to 2015-16**

Tier	Applicable Introduction Value	Approx. Number of Companies	2011-12 Current Fee & Charge	2012-13 Proposed Fee & Charge	2013-14 Proposed Fee & Charge	2014-15 Proposed Fee & Charge	2015-16 Proposed Fee & Charge
1	\$1 - \$99,999	2,720	\$395	\$395	\$133	\$138	\$143
2	\$100,000 - \$499,999	750			\$395	\$405	\$415
3	\$500,000 - \$4,999,999	940	\$1,577	\$1,857	\$1,857	\$1,980	\$2,035
4	\$5,000,000+	380	\$9,201	\$14,300	\$18,475	\$19,800	\$20,350
<b>Total amount recovered</b>			<b>\$6,349,410</b>	<b>\$8,550,230</b>	<b>\$9,424,090</b>	<b>\$10,064,310</b>	<b>\$10,346,110</b>

The table below summarises the applicable late penalties for NICNAS’s Registration Fees and Charges for the period 2012-13 to 2015-16 based on an estimated indexation rate. These penalties are not cost recovery charges for the purposes of the cost recovery policy (see section 4.5).

**Table 16 – Summary of NICNAS Registration Late Penalty Charges from 2012-13 to 2015-16**

Tier	Applicable introduction value	2011-12 current late penalty (\$)	2012-13 proposed late penalty (\$)	2013-14 proposed late penalty (\$)	2014-15 proposed late penalty (\$)	2015-16 proposed late penalty (\$)
1	\$1 - \$99,999	59	100	105	105	110
2	\$100,000 - \$499,999	59	100	105	105	110
3	\$500,000 - \$4,999,999	237	185	185	200	205
4	\$5,000,000+	1,380	1,430	1,850	1,980	2,035

The summary table below shows NICNAS costs and cost recovery revenue over the period of this CRIS. The table demonstrates how cost recovery fees and charges are commensurate with NICNAS costs.

**Table 17 – Summary of NICNAS Revenue and Expenses from 2012-13 to 2015-16**

Activity	2012-13	2013-14	2014-15	2015-16
<b>Revenue</b>				
Fee for Service	\$2,629,500	\$2,814,700	\$2,905,150	\$3,006,500
Registration	\$8,550,230	\$9,424,090	\$10,064,310	\$10,346,110
<b>Total Revenue</b>	<b>\$11,179,730</b>	<b>\$12,238,790</b>	<b>\$12,969,460</b>	<b>\$13,352,610</b>
<b>Expenses</b>				
Fee for Service	\$2,629,500	\$2,814,700	\$2,905,150	\$3,006,500
Registration	\$8,748,507	\$9,396,612	\$10,059,570	\$10,284,383
<b>Total Expenses</b>	<b>\$11,378,007</b>	<b>\$12,211,312</b>	<b>\$12,964,720</b>	<b>\$13,290,883</b>
<b>Difference</b>	<b>-\$198,277</b>	<b>\$27,478</b>	<b>\$4,740</b>	<b>\$61,727</b>

## **7 ONGOING MONITORING**

### ***7.1 Monitoring Mechanisms***

NICNAS has developed a robust ABC system to support cost recovery objectives. NICNAS will review the ABC assumptions and business rules on a regular basis to ensure that fees and charges are aligned with costs.

The primary mechanism used to monitor NICNAS activities, performance and costs is consultation with industry and government, currently undertaken through the NICNAS IGCC. Under the terms of reference set by the Minister, the IGCC reviews, among other things, the utilisation of resources against NICNAS objectives. The IGCC meets at least twice a year.

### ***7.2 Stakeholder consultation***

NICNAS will consult with the chemical industry and other NICNAS stakeholders over these proposed fee and levy changes through publication of this draft CRIS on the NICNAS website, promotion to all stakeholders on the NICNAS database and stakeholder meetings. NICNAS will provide opportunities for feedback on the proposed changes.

The consolidated outcomes of the stakeholder consultation in relation to the draft CRIS will be inserted here in the final version.

### ***7.3 Periodic Review***

The Cost Recovery Guidelines require that all cost recovery arrangements are subject to periodic review no less frequently than every five years. It is intended that the next process will be undertaken in 2015-16 unless there are changes to the NICNAS cost recovery arrangements as a result of the Better Regulation Ministerial Partnership, in which case a new CRIS will be developed earlier.

## **8 COST RECOVERY LINKS**

- The Australian Government Cost Recovery Guidelines and the accompanying Finance Circular can be found at:  
*<http://www.finance.gov.au/financial-framework/financial-management-policy-guidance/cost-recovery.html>*
- For proposals that involve regulation or amendment to regulation that affects business, a Regulation Impact Statement is required. Contact the Office of Best Practice Regulation for further information below:

*<http://www.finance.gov.au/obpr/index.html>*

**APPENDIX A - SUMMARY OF STAKEHOLDER COMMENTS TO QUESTIONS IN CRIS DISCUSSION PAPER AND NICNAS RESPONSE**

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<b>REGISTRATION FEE STRUCTURE AND TIER 1 REGISTRANTS</b>		
<p>Q1. What services do tier-1 registrants require from NICNAS?</p>	<p>It was generally agreed that tier-1 registrants want guidance from NICNAS in relation to federal and state chemical management regulations, best practice and chemical risk awareness information used by particular industries in relation to risk on the public and the environment.</p>	<p>NICNAS recognises clear opportunities for improvement relating to engagement with tier-1 registrants – particularly those at the lower end of tier-1, as well as those in less regular contact. Specific focus areas include an explanation on the rationale for fees and charges, scope of the scheme, compliance requirements and implementation of reforms.</p>
<p>Q2. Are there other fee structures which would provide a more equitable distribution of the funding burden?</p>	<p>Many respondents were concerned that tier-1 fees and charges were not equitable given the tier-1 threshold \$1-\$499,999. A range of views were expressed regarding tier-1, including that the tier is too large i.e. introducers of chemicals up to \$500,000 in value pay the same fee as introducers of industrial chemicals worth only \$10,000, resulting in excessive cost to small businesses and a lack of value for registration i.e. NICNAS provided services.</p> <p>Another view was that NICNAS could replace the current tier fee structure with a continuous scale, under which registrants would pay a fixed proportion of the value of their products. This would be a more equitable approach and ensure registrants with large product volumes pay their fair share thus establishing a better connection between product value and fee, or, that it would be more equitable if fees were levied as a proportion of profit, just like the company tax system.</p>	<p>NICNAS notes stakeholder views and has explored alternative fee structures. An amended four-tier fee structure has been built-in to the draft CRIS. Under the proposed model scheduled to begin in 2013-14, the current tier-1 would be split into two separate tiers to distinguish low volume introducers below \$100,000 value. The proposed new tier-1 threshold would be \$1-\$99,999, and the threshold for tier-2 would be \$100,000 - \$499,999. The thresholds for tiers-3 and -4 would remain at status quo, i.e. \$499,999-\$4,999,999 and ≥ \$5,000,000, respectively. The registration fees and charges will be adjusted accordingly (see section 4.4 of draft CRIS).</p> <p>The activity based costing (ABC) study found that to charge all introducers an equal percentage of the introduction value would result in the maximum fee payable equalling approximately \$1.8 million per annum. This system would result in a dramatic increase in fees for large introducers, an increased administrative impost on NICNAS, and a potential threat to the financial stability of NICNAS (as NICNAS would be reliant on the fees from a small number of introducers). Therefore, this option would not present an efficient and cost effective framework for NICNAS registration.</p>

NICNAS Cost Recovery Impact Statement

APPENDIX A

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q3. If a higher minimum threshold value for tier-1 registration is introduced, how does NICNAS ensure the introducers who fall below this threshold are aware of their obligations under the <i>IC(NA) Act</i>?</p>	<p>Some submissions were not in favour of changing the tier fee structure stating for example, that the current structure is reasonably fair as large companies trading \$50 million plus may have a smaller range of chemical ingredients.</p> <p>It was also noted that as there was no modelling available of the quantum of income needed for ongoing NICNAS operations, a change to tier-1 was not supported.</p> <p>The majority of CRIS online survey responses (76%) supported no registration fees for small users of chemicals.</p> <p>Many tier 1 respondents supported paying fees but were concerned that the tier structure was inequitable, i.e. a micro business included in a tier with a chemical value of \$499,999.</p> <p>Another suggestion was to introduce pro-rata fees for new businesses starting up mid-cycle.</p> <p>Another view was that all importers who are registered with Customs should be registered with NICNAS and information sharing should occur between the government agencies.</p>	<p>NICNAS notes stakeholder views. NICNAS has not proposed a change to the minimum threshold value for tier-1 and registration has been retained for all introducers, but NICNAS has changed the fee arrangements for tier-1 introducers.</p> <p>NICNAS has undertaken modelling to determine the cost of operations using ABC methodology and the details are incorporated into Draft CRIS (see section 3.3).</p> <p>The registration fee (not the charge) is paid by all registrants regardless of the level of registration. The registration fee is only used to recover the administrative cost associated with maintaining the register of industrial chemical introducers. This includes the costs of processing new registration applications and applications for renewal, maintaining details on the NICNAS corporate database, providing advice regarding the registration process, and complying with the requirements of the FMA Act.</p> <p>The amount of administration/time expended on processing registration applications/renewals does not change depending on the time of the year at which an application is made.</p> <p>NICNAS has a current Memorandum of Understanding with Australian Customs in relation to compliance measures.</p>
<b>REGISTRATION TIMEFRAME</b>		
<p>Q4. Is the application of a late penalty fee a deterrent to late payment of fees?</p>	<p>It was generally agreed that late payment penalties are a deterrent to late payment of registration fees.</p> <p>There was a view was that the current charge of 15% is excessive suggesting 10-12% would be more appropriate.</p> <p>Respondents also noted that in their view penalty payments are an administrative burden on NICNAS.</p>	<p>NICNAS notes stakeholder views. Penalties for late registration renewal applications are mandated under the <i>IC(NA) Act</i>, but NICNAS has examined this issue further. In the Draft CRIS, NICNAS has proposed using a revised penalty fee in 2012-13 of \$100.00, or 10% of the sum of the registration fee and any applicable charge, whichever is greater (rounded to the nearest \$5.00). This would recover costs and continue to act as a reasonable deterrent for late payments (see section 4.5 of the Draft CRIS).</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q5. What other mechanisms could be used to encourage registration payments to be made on time?</p>	<p>Some submissions suggested other options such as quarterly payments, reduced fee bonus for early payment and Customs intervention resulting in goods being held for serious intentional non-compliance.</p> <p>Industry commented that registration non-compliance or late payment should result in audit.</p> <p>The majority of online respondents (83%) strongly supported payment reminders and early bird incentives (81.5%) as an effective compliance strategy.</p>	<p>NICNAS encourages registrants to pay on time by issuing invoices weeks prior to the due date and by placing notices on the website, chemical gazette and NICNAS Matters. NICNAS has also recently adopted some of the suggestions made by stakeholders to further improve on time payments, such as sending electronic payment reminders and making phone calls to registrants before the payment due date.</p> <p>For serious intentional non-compliance, NICNAS has previously undertaken enforcement actions, including seizure of goods.</p>
<p><b>REGISTRATION CYCLE</b></p>		
<p>Q6. Would the introduction of an optional multi-year registration cycle be beneficial to industry and why? If so what would be the optimal period per cycle, e.g. 2 years, 3 years?</p>	<p>Many respondents did not support a change to the registration cycle providing a range of reasons, such as a change may incur further administration costs to NICNAS.</p> <p>Online responses (56% of 1069 respondents) from the public &amp; Industry preferred the existing model.</p>	<p>NICNAS notes the strong support for the existing model. No change is proposed in the Draft CRIS.</p>
<p>Q7. Would the alignment of the NICNAS registration cycle with the financial year be beneficial? Please supply supporting information.</p>	<p>There was a mixed response with some favouring aligning the registration year with the financial year or calendar year, and others argued for no change to the registration cycle.</p> <p>Other views from Government respondents favoured a change to the registration cycle.</p> <p>40% of the 1069 respondents to the online survey favoured aligning the registration year with the financial year but there was a mixed view on whether to align with the financial or calendar year.</p>	<p>NICNAS notes stakeholder views. As there were mixed responses and no consensus among stakeholders that favoured a change to the registration cycle on whether it should be aligned with the financial year or calendar year, no change is proposed in the current Draft CRIS.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q8. What issues would need to be considered in relation to the appropriateness and extent of cross subsidisation of new chemical assessments, and what approaches could be taken to manage these?</p>	<p>One view was that cross-subsidisation was due to introduction of low regulatory chemical concern categories, adding that it is essential to lower costs for new innovative chemicals.</p> <p>Another view supported minor cross subsidisation up to 20%, which would allow acceptable minor flexibility ensuring functions do not stop due to lack of funds.</p> <p>Another respondent supported cross subsidisation up to 15%.</p> <p>Response from some industry stakeholders was that there was no transparency to activity based costing for all areas of activity, making it difficult to assess the level of cross-subsidisation and assess its relevance.</p> <p>Industry stakeholders also supported direct costs associated with the assessment process only being charged to businesses notifying the new chemical.</p> <p>Another view was that benchmarking is required to determine assessment performance for comparable work by comparable international agencies.</p>	<p>Cross-subsidisation occurs when one user group pays more or less for a service than the actual cost of providing the service and the resulting surplus or deficit is used to offset the costs of services to other groups or is recuperated from other cost recovery funds.</p> <p>Cross subsidisation is not supported in the government’s cost recovery guidelines (for further details, see section 1.3 of the Draft CRIS).</p> <p>In the Draft CRIS the fees for services have been based on the cost of undertaking the current fee for service activities during the period of the ABC study, from 1 April 2009 to 31 March 2010. The ABC study included only the time spent directly on the assessment (for further details see section 3.5 of the Draft CRIS).</p> <p>In general, fees for assessment of chemicals of lower regulatory concern are lower in cost, matching the lesser effort required to assess the chemicals. The activities included in the assessment fees are different and narrower compared to the previous (2005) CRIS.</p>
<p><b>NEW CHEMICAL FEE STRUCTURE</b></p>		
<p>Q9. Should the funding mechanism for screening submissions be changed? What are the advantages and disadvantages of a non-refundable screening fee for new chemical assessments as an incentive to achieving better quality submissions?</p>	<p>A number of respondents did not support screening fees suggesting that NICNAS has not provided adequate costing data to demonstrate the efficiency of the screening system. Some respondents suggested that further stakeholder engagement is required to assess current NICNAS performance against statutory timeframes.</p> <p>Another view was that work should be undertaken to determine suitability of the screening. Another view offered conditional support for a screening fee but that the assessment clock must start if a screening fee is introduced.</p> <p>Non-refundable screening fees were supported by 43% of respondents to the online survey. There was significantly higher support amongst government stakeholders.</p>	<p>NICNAS notes stakeholder views.</p> <p>Preliminary analysis of the number of applications for which the assessment commenced on receipt of the notification over a 3 year period 2007-2010 indicates that the proportion increased gradually in the case of certificate assessments, however no improvement was observed in permit applications.</p> <p>Non-refundable screening fees will discourage notification submissions that do not contain the required data, or have insufficient information. Based on calculations through the ABC study, a non-refundable screening fee of 15% of the value of each assessment fee is proposed to cover the preliminary evaluation work that is required for each application before the assessment clock can start. This fee would form a component of the overall assessment fee. The issue of screening fees are examined in more details in the draft CRIS (section 4.1.3).</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q10. What are the advantages and disadvantages of industry receiving a rebate of up to 15% of the new chemicals application fee when submissions are made using an agreed electronic template?</p>	<p>Electronic template rebate was generally supported however, stakeholder responses raised some questions:</p> <p>As the typical rebate is 5%, NICNAS should undertake data analysis of the internal application process to ensure internal processes are reviewed.</p> <p>Another view was that the rebate should be cancelled and use of the electronic template should be compulsory.</p> <p>Another view was that additional information on the likely rebate level and assurance of a fee deduction from the current overall fees is needed. Another respondent suggested that discounts must be supported by productivity gains by NICNAS.</p> <p>Discounts for electronic submissions were strongly supported (78%) across all respondent groups (953) and a small number of respondents (6%) were opposed.</p>	<p>NICNAS notes stakeholder views. The ABC study highlighted that electronic template submissions do not necessarily result in a reduction in effort by NICNAS, and in some cases, these assessments took longer to complete. It is proposed in the draft CRIS that the rebate be removed and assessment fees represent the average cost of undertaking each assessment regardless of whether or not an electronic template was used (see section 4.2.2 of draft CRIS).</p>
<p>Q11. What are the advantages and disadvantages of changing the mechanism for recovering the cost of the preliminary review of changed circumstances (of an assessed new chemical) and making a decision on whether a secondary notification is warranted? Should this be a fee for service?</p>	<p>One response was that the fee would be justified if there were clear guidelines for requiring secondary notification. Another view was that secondary notification costs are part of NICNAS staff training costs and therefore should not be covered.</p> <p>On the question of the preliminary review of changed circumstances, the majority of respondents do not support fee for this service suggesting that the imposition of a fee could act as a disincentive to notify NICNAS of a changed circumstance.</p>	<p>NICNAS notes stakeholder views. A fee for this service is not proposed in the Draft CRIS.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<b>REGULATORY REFORM ACTIVITIES</b>		
<p>Q12. What factors should be considered in determining the level of reform activity NICNAS undertakes?</p>	<p>It was generally recognized that there are a number of factors determining the level of reform activity in particular, benefits to industry and community, improving sustainability, organisation reform capacity, human health and environment protection.</p> <p>Another view was that a review of NICNAS reform activities should be undertaken.</p>	<p>NICNAS notes stakeholder views.</p> <p>NICNAS continues to reform its programs in response to stakeholder concerns and emerging issues within the context of COAG principles and guidelines. Consistent with its Community Engagement Charter, all NICNAS reforms are undertaken in full consultation with the industry, community and various levels of government. The cost of reform activities are analysed in the Draft CRIS and presented in table 2 of section 3.3. An analysis of reform activities that have been undertaken over the past five years is presented in Appendix C.</p> <p>In the main, reforms implemented to date have afforded significant benefits to the chemicals and plastics industry while maintaining or enhancing health, safety and environmental standards. NICNAS reforms are benchmarked against international best practice and aim to harmonise regulatory requirements with major trading partners, where possible. Significant reforms have been made to the scheme since 1997 and a process of evaluation will enable NICNAS to identify issues that need to be considered when undertaking new reform activities.</p>
<p>Q13. What are the implications of NICNAS charging a special levy or fee to a particular industry sector where reform activities are specific to that sector?</p> <p>Q14. How could this levy be structured alongside a multi-year funding cycle?</p>	<p>Industry response was divided with regard to charging a special levy on a particular industry sector, noting that fairness of levy application was a key element for consideration.</p> <p>Another view was to implement reform under the Canadian Approved Foreign Scheme which may provide benefits i.e. lower assessment costs.</p> <p>It was also suggested that reform activities should focus on ways to encourage companies to introduce innovative chemicals that improve the sustainability of Australia.</p> <p>Online survey responses regarding a fee for service for sector-specific activities were supported by 51% of the 910 respondents.</p>	<p>NICNAS notes stakeholder views. Given that there were mixed responses in regards to a special levy for particular industry sectors, NICNAS is not proposing to move to sector-specific levies at this stage.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<b>REGULATORY IMPACT ASSESSMENTS</b>		
<p>Q15. What is the best manner in which the cost of regulatory impact assessments can be recovered? Should these costs be incorporated into the fee when it relates to a fee for service activity? Should the cost of regulatory impact analyses be included as an overhead cost and therefore funded from the registration levy?</p>	<p>Most respondents to this question did not support a fee for service for this activity and noted that a regulatory impact statement is a government requirement and therefore should be paid for by government.</p> <p>Another view was that activities could be funded through registration levy or government revenue as regulation costs should be borne by the community, government, non-government sectors and industry.</p> <p>It was suggested that as CRIS and RIS are government business, the policy body rather than the statutory scheme should undertake associated work.</p>	<p>NICNAS notes stakeholder views. The Australian Government Cost Recovery Guidelines state that policy development and parliamentary servicing functions that are integral to the activity are appropriate and efficient to include in cost recovery. Regulatory impact assessments and cost recovery reviews are integral to the functions of NICNAS, no changes to the current arrangements are proposed and these activities will continue to be funded by the registration levy.</p>
<b>NICNAS CORPORATE GOVERNANCE, BUSINESS PRACTICES</b>		
<p>Q16. What is an adequate level of reserves for NICNAS to enable the organisation to continue its business?</p>	<p>Industry respondents suggested that NICNAS engage consultants whenever the workload demands, suggesting that this strategy of recruiting staff as needed may increase NICNAS reserve.</p> <p>Another view was that the NICNAS reserve should cover one full year of activities.</p> <p>Community stakeholder view was that an increase in NICNAS reserve would allow the agency to function independently of registration or other fees.</p>	<p>NICNAS notes stakeholder views. NICNAS currently holds a contingency fund of 10% (a little over one month's operating expenses). Other comparable agencies hold a three month operating expense reserve and therefore NICNAS proposes to increase the reserve until it reaches three months operating expenses. See section 4.7 of the draft CRIS for details on NICNAS reserves.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q17. What strategies could be used to improve the predictability of NICNAS annual income?</p>	<p>Suggested strategies included seeking guidance from the DoFD regarding reserve levels or that a levy based on cents per import dollar value may improve the predictability of NICNAS annual income.</p> <p>Industry stakeholders stated that NICNAS should accept fluctuating economic levels that industry must also endure.</p> <p>Another view held by a number of industry stakeholders was that they were unaware of this issue regarding predictability of income for NICNAS, noting that the income stream appears quite robust.</p>	<p>NICNAS notes stakeholder views. The assumptions used to predict the revenue during the period of the CRIS will be subject to stakeholder consultation through the draft CRIS.</p>
<p><b>NICNAS CAPABILITY</b></p>		
<p>Q18. What factors should be considered when determining the appropriate level of investment in training and new assessment technologies?</p>	<p>It was emphasized in the responses that building NICNAS staff capability should focus on measurable outcomes and overall benefits to NICNAS business, i.e. training specific to improving efficiency and effectiveness in line with industry standards.</p> <p>Another view was that training and new assessment methodology costs should come directly from fees that industry pays each year (including money remaining from tier-1).</p> <p>Comments also suggested that return on investment should be the key determining factor in determining the appropriate level of investment.</p> <p>Another view was that consideration should be given to the related benefits across NICNAS, so improving outcomes in the areas of reform and regulatory functions.</p> <p>Another response emphasised that NICNAS should be increasing its knowledge of international risk assessment methodologies ensuring that Australian assessment practices are current, thus delivering regulation for the protection of Australian human health and the environment.</p>	<p>NICNAS notes these views. To date, NICNAS has invested in increasing its awareness and understanding of risk assessment methodologies used internationally, as well as enhancing staff capabilities in current simulation techniques. Formal arrangements with overseas authorities and participation in international harmonisation activities also improve NICNAS's capabilities and provide return for investment through their utilisation in the assessment programs. NICNAS proposes to continue the same level of training and investment in new assessment technologies as in previous years.</p>

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QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<b>INDUSTRY COMPLIANCE</b>		
<p>Q19. What factors should influence the amount of compliance effort spent on a particular activity?</p>	<p>It was generally agreed that compliance efforts should be influenced by enforcement requirements and industry education. Another suggestion was that the import monetary value, and risk to worker, public health and the environment should influence the amount of compliance effort expended.</p> <p>The views included the suggestion that NICNAS evaluate its outreach activities to improve the effectiveness of the activities.</p> <p>Online survey response indicated that at least 80% of the 802 respondents believed auditing is significantly important to NICNAS business.</p>	<p>NICNAS notes stakeholder views. Compliance effort is aligning with introduction values and is a key component that underpins NICNAS risk management strategies. NICNAS proposes to continue a similar level of compliance activity as for previous years.</p> <p>NICNAS notes strong support for auditing.</p>
<p>Q20. What factors should be considered when determining the level and type of outreach activities undertaken?</p>	<p>Respondents supported the need for ongoing stakeholder engagement noting specifically that outreach activities should:</p> <ul style="list-style-type: none"> <li>- be consistent with NICNAS’s mission to increase industry awareness,</li> <li>- address market failure,</li> <li>- relate to the introduction of new product types,</li> <li>- meet stakeholder demand, and</li> <li>- meet community expectations.</li> </ul> <p>Another view was that international outreach should be aligned with government trade policy with all resource transfers paid for by government i.e. Department of Foreign Affairs and Trade. NICNAS should seek to expand both the level and type of outreach activities whilst constantly evaluating all activities to improve the effectiveness of these activities.</p>	<p>NICNAS will continue to undertake outreach activities and at a similar level as in previous years and will consider stakeholder views when preparing and delivering these services.</p>

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QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<b>COST RECOVERY DOCUMENTATION</b>		
<p>Q21. Are there any specific items you would like to see included in a document outlining NICNAS's cost recovery policy and procedures?</p>	<p>Industry stakeholders responded that the methodology of cost recovery should be included in the CRIS and include information relating to core regulatory activities, sustainable chemicals, government business, i.e. accounts of the department, training costs, accommodation and analysis of such expenditure showing benefits to the registrants.</p>	<p>NICNAS has developed a Cost Recovery at NICNAS – Principles and Practices Manual June 2011, to establish overall principles to be used in the formulation of NICNAS fees and charges. The manual is used by NICNAS when considering appropriate resourcing levels and fees and charging structures and will be updated following any changes to NICNAS's cost recovery procedures as a result of the CRIS.</p>
<p>Q22. Is there a reason to expand the definition of a chargeable person to include downstream users of industrial chemicals? What factors should be considered in coming to this view?</p>	<p>The majority of responses did not support charging downstream users for a number of reasons, including; charging downstream users is double dipping, and it would increase NICNAS administrative cost with no quantified benefit.</p> <p>The online survey response showed strong support from Government respondents to expand the definition of a chargeable person.</p> <p>Online responses (939) were closely divided on this question which was true across all groups. 43% supported and 36% opposed expanding the definition, with the exception of government respondents, who tended to support the option more than other groups.</p>	<p>NICNAS notes stakeholder views. This issue is not being progressed in this CRIS.</p>
<p>Q23. What factors should influence the indexation model for adjusting fees and charges?</p> <p>Q24. What is the implications of introducing an automatic annual adjustment?</p>	<p>The majority of stakeholders do not support automatic indexation and raised concerns such as:</p> <ul style="list-style-type: none"> <li>- it would do little to encourage cost saving initiatives;</li> <li>- NICNAS charges will not be responsive to economic peaks and troughs.</li> </ul> <p>Another view was that each tier could be adjusted for inflation in sensible increments i.e. \$50K &amp; \$500K.</p> <p>Online survey respondents most commonly opposed automatic indexation.</p>	<p>NICNAS notes stakeholder views.</p> <p>NICNAS is seeking stakeholders' views on the proposed indexation of fees and charges as outlined in section 6 of the Draft CRIS to allow better predictability of available resource levels for NICNAS in order to plan projects that run over multiple years. NICNAS will monitor actual costs to ensure that indexation rates are reflective of cost change rates.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
<p>Q25. What do you believe is the most equitable manner in which to cost recover these activities (e.g. training on notification processes and implemented reforms; and other technical services related to industrial chemicals)? Should it be through a fee for service or a levy?</p>	<p>Stakeholders supported a levy or fee for service to support outreach activities and training, suggesting the levy be based on a dollar import value. Further suggestions were that a fee for service is appropriate, particularly as it will educate companies to seek advice from NICNAS.</p> <p>Another view was that government should fund all activities.</p> <p>Of the online respondents, 49% supported a fee for stakeholder training. Support for costs to be raised through general registration charges was 32%. Some significant differences across groups included: higher support for stakeholder training to be covered in the general registration charge amongst tier-3 registrants (48% compared to 32%); and lower support for cost recovery via the registration charge amongst the industry association/peak body group (8% compared to 32%).</p>	<p>NICNAS notes stakeholder views.</p> <p>NICNAS provides information on industrial chemicals and industrial chemical regulation through the NICNAS website, corporate publications, consultative committees and answering inquiries. NICNAS also delivers targeted communications (such as training for notifiers and chemical introducers) to ensure they are more aware of their legal obligations and health and safety issues relevant to the chemicals in which they trade. NICNAS is proposing to recover these costs through the NICNAS registration charge. Recovery of these costs through the NICNAS registration charge is considered to be cost-effective.</p>
<p><b>COST RECOVERY DOCUMENTATION</b></p>		
<p>Q26. Are there any other issues with the NICNAS fees and charges you would like to see addressed in the CRIS?</p>	<p>Respondents supported the use of international assessments to increase NICNAS efficiency and listing of NICNAS activities for discussion as to whether they are core or non-core activities.</p> <p>Another view was to focus on improving efficiency and effectiveness through productivity gains.</p> <p>Some others expressed views that it is in the public interest for NICNAS to be funded to engage with stakeholders contributing to best practice industrial chemical regulation in Australia. NICNAS must engage with a diverse range of stakeholders including,</p> <ul style="list-style-type: none"> <li>- down stream users;</li> <li>- peak environmental groups;</li> <li>- public health groups; and</li> <li>- research institutes and academia.</li> </ul> <p>Another response suggested that the CRIS review discuss</p>	<p>NICNAS notes stakeholder views. Through the CRIS, NICNAS has assessed and confirmed that all current activities are appropriate to cost recover under the Australian Government Cost Recovery Guidelines. NICNAS has implemented a range of efficiencies to minimise cost increases, e.g. streamlined procedures for processing registration payments and whole of government travel arrangements. Refer to section 3.3.1 of the draft CRIS and Appendix C for further details.</p>

QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
	<p>whether some or all of NICNAS's fees are contestable.</p> <p>Some respondents offered comments regarding the Productivity Commission report:</p> <ul style="list-style-type: none"> <li>- non integral risk management functions to NICNAS;</li> <li>- primary function of administering a chemical assessment should be identified via the CRIS and be removed as recommended by the PC;</li> <li>- PC recommendations regarding NICNAS's future role as a scientific assessment body and the removal of a number of functions i.e. administering the Cosmetic Standard;</li> <li>- removing responsibility for implementing the Rotterdam Convention to be implemented immediately as such changes would deliver immediate cost savings to industry.</li> </ul>	<p>Productivity Commission recommendations are outside the scope of the CRIS Review and will be considered under a review undertaken as a Better Regulation Ministerial Partnership between the Minister for Finance and Deregulation and the Minister for Health and Ageing (<a href="http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr11-ck-ck037.htm">www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr11-ck-ck037.htm</a>).</p>
<b>PRIORITY ASSESSMENT – EXISTING CHEMICALS</b>		
<p>Q27. What are your views on the benefits of addressing the regulatory gap through prioritisation and undertaking this project within a reasonable period of time? Can you see any additional benefits other than those identified?</p>	<p>Industry responses were supportive of the program but question how it will be undertaken. Respondents supported using outcomes from similar exercises by REACH (Europe), Canada &amp; USA noting the potentially large cost to industry to provide information.</p> <p>Another view was the program is in the public's interest and that use of overseas outcomes should be qualified with adequate considerations for an Australian context.</p>	<p>NICNAS notes stakeholder views. NICNAS plans to implement a program to greatly accelerate the assessment of existing chemicals in Australia through a screening and prioritisation process. The assessment and prioritisation framework involves a staged approach, with the progression and evaluation of stage one over a four year timeframe. The focus of stage one will be on approximately 3000 chemicals and will include an external review process. An overview of this program is described in section 5 of the draft CRIS.</p>
<p>Q28. What is the most equitable manner to raise funds to support prioritisation of chemicals on the</p>	<p>Community stakeholders expressed a view that as industry has been the main beneficiary of the absence of chemical assessments for AICS-listed chemicals, via increased and often unreported costs to the environment and public health sector, full cost recovery from industry in their view is</p>	<p>A proposed cost recovery model and for the accelerated assessment program and charging structure is included in the draft CRIS (section 5).</p>

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QUESTIONS	SUMMARY OF STAKEHOLDER COMMENTS	NICNAS RESPONSE
inventory?	<p>justified.</p> <p>It was also the view of community stakeholders that the assessment of existing industrial chemicals must be accelerated. Adding that as industry has had free run, the responsibility to ensure chemicals pose no risk lies with industry and simply because a chemical has been used for many years does not mean it is safe.</p> <p>Some industry comments supported the COAG views that industry funding of this activity is appropriate as it was to industry's advantage that the 38,000 chemicals were 'grandfathered' onto the AICS.</p>	

## **APPENDIX B - BENCHMARKING INDICATORS OF AGENCY COSTS**

The purpose of this study is to benchmark indicators of agency cost associated with industrial chemical regulation. This study is not a comprehensive benchmarking study, but gives a broad overview of NICNAS's costs relative to other comparable regulators.

This study looks at NICNAS's costs in comparison with national and international chemical regulatory authorities, including the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA), Health Canada/Environment Canada, the United States Environmental Protection Agency (US EPA) and the European Chemicals Agency (ECHA).

### ***B.1 National Comparisons***

The following information has been gathered from public sources.

#### **B.1.1 NICNAS**

NICNAS is the Australian Government regulatory authority responsible for the assessment of industrial chemicals, which include cosmetics. NICNAS is a chemical entity-based scheme. Under NICNAS chemicals are regarded as Existing Chemicals, which are those on the Australian Inventory of Chemical Substances (AICS), or New Chemicals. NICNAS independently assesses industrial chemicals for their risks to the Australian people and the environment.

NICNAS is a 100 per cent cost recovered agency. Application fees are paid by manufacturers and importers (introducers) for the assessment of New Chemicals and an annual charge (levy) is paid by chemical introducers based on the value of introduced (by importation or manufacture) industrial chemicals.

#### **B.1.2 The Australian Pesticides and Veterinary Medicines Authority (APVMA)**

The APVMA is the Australian Government statutory authority responsible for the assessment and registration of pesticides and veterinary medicines in Australia, and for their regulation up to and including point of retail sale. The scheme is product-based. The APVMA independently evaluates the safety and performance of pesticides and veterinary medicines intended for sale, ensuring that the health and safety of people, animals and crops, the environment and trade are protected. To ensure that only those products that meet health and safety requirements are supplied, the APVMA constantly monitors the market for compliance. The APVMA also reviews registered chemical products to ensure they continue to meet contemporary standards.

The APVMA is a cost recovery agency, collecting the majority of its operational income from registrants of pesticides and veterinary medicines. Registrants pay application fees to register new products and active constituents, amend current registrations, or apply for a permit, such as authorising "off label" uses of a pesticide and veterinary medicine. An annual fee is payable each year to renew the registration of a product. Registrants also pay an annual levy based on sales (and other disposals) of their registered products.

The APVMA total income for 2009-10 was \$24.36 million [APVMA Annual Report 2009-10]. Total industry contributions were \$23.34 million (94 per cent of total income), of which approximately 71 per cent were recovered via levies and 29 per cent via fees.

### **B.1.3 The Therapeutic Goods Administration (TGA)**

The TGA is Australia's regulatory authority for therapeutic goods, which include medicines, medical devices and human blood, blood products and tissues. The overall purpose of the TGA is to protect public health and safety by regulating therapeutic goods that are either imported or manufactured, or exported from Australia. The scheme is product-based.

The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. The TGA regulates therapeutic goods through: pre-market assessment; post-market monitoring and enforcement of standards; and licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts. Most products for which therapeutic claims are made must be assessed by the TGA and entered on to the Australian Register of Therapeutic Goods (ARTG) before they can be marketed in Australia. In general Australian therapeutic product manufacturers are required to be audited and licensed by the TGA and overseas manufacturers are required to meet equivalent standards. The TGA also regulates fresh blood, blood components and banked tissues. These products are not generally included on the ARTG; their regulation is through audit and licensing of manufacturers and compliance with standards.

The TGA recovers the full cost of its regulatory activities through fees and charges from industry. The TGA collects its revenue primarily through annual charges, evaluation and assessment fees, and licence fees. The TGA total income for 2009-10 was \$101.9 million [Department of Health and Ageing Annual Report 2009-10] with total industry contributions being approximately 96 per cent of the total income.

### **B.1.4 Comparison with NICNAS**

The APVMA, TGA and NICNAS are broadly similar in that they all undertake pre-market assessment activities and post-market assessments and compliance activities to ensure that the chemicals under their regulatory authority are safe. Likewise, each agency recovers their costs for assessment via a fee for service and each agency has an annual levy or registration payment to recover the cost of other activities, including general functions not specific to a service.

The regulatory frameworks within each agency, however, are different. Both the APVMA and the TGA assess products and have responsibility for ensuring product efficacy and labeling requirements, whereas NICNAS is a chemical entity-based scheme with emphasis on assessment of the risks of individual chemicals. The TGA has an emphasis on public health, whereas both the APVMA and NICNAS also assess effects on the environment and worker health and safety. These framework differences have an impact on the scope of assessment and consequently the costs of assessment.

**B.1.4.1 Comparison of Staffing versus Revenue and Expenses****Table B1: Comparison of staffing versus revenue and expenses: TGA, NICNAS, and APVMA**

Year	Agency	Staff <sup>11</sup>	Total Income	Total Expenses	Ratio (income/staff)	Ratio (expense/staff)
08-09	TGA	585	92.46 M	94.44 M	158 K	161 K
08-09	NICNAS	60	8.73 M	8.98 M	148 K	152 K
08-09	APVMA	159	24.83 M	25.86 M	156 K	162 K
09-10	TGA	615	101.9 M	101.3 M	166 K	165 K
09-10	NICNAS	68	8.74 M	8.75 M	128 K	129 K
09-10	APVMA	155	24.36 M	26.06 M	157 K	168 K

The data shows that NICNAS has approximately one-tenth the staff numbers of TGA and slightly less than half the staff numbers of the APVMA. A comparison of staff numbers compared to total income (and total expenses) for each agency shows that staffing levels are comparable relevant to the size of the business, with some variations likely over the short-term due to factors such as full-time versus part-time staff, administrative overheads and consultancy expenses. As expected, these variations would be more noticeable in a smaller organisation, i.e. NICNAS.

**B.1.4.2 Comparison of Assessment Fees**

The NICNAS assessment fees for new chemicals range from \$2,841 to \$16,782 (for year 2011-12) depending on the scope of the assessment and the volume of chemical being introduced. A fixed fee is applicable for the assessment 'category'.

While noting the differences in the assessment frameworks, the TGA evaluation fees range from \$7,300 to \$60,700 (for year 2011-12), based on total page count(s) of clinical or toxicological data per submission for listed, over-the-counter and complementary medicines, and registered devices. The TGA has a greater range of fees or evaluation 'categories'.

The APVMA fee for the assessment of a new active ingredient in a product is up to \$25,775 (for year 2011-12) depending on the scope of the assessment and size of the chemistry and toxicological data package. The fee for the approval of a new agricultural or veterinary product containing a new active ingredient, registration of the product and approval of the product label is up to \$53,745 (for year 2011-12), again depending on the scope of the assessment. As for the TGA, the APVMA has a wide range of assessment options available to introducers of new products. The APVMA assessment fees are subsidised by their annual levy, with the fee expected to represent approximately 40% of the full cost.

As a direct comparison, NICNAS assessment fees are lower than the TGA or APVMA. However, the scope of assessment is usually greater for the TGA and APVMA than NICNAS. For example, the toxicological package required for the evaluation of therapeutics and pesticides is generally larger than that routinely required by NICNAS.

<sup>11</sup> Includes full-time, part-time, in-operative and out-posted staff.

NICNAS has fees for a number of administrative applications, for example, application for information to be exempt from publication and application to vary an assessment report or information requirements. These fees (2011-12) are lower than assessment fees and range from \$662 to \$1,988.

The TGA has fees (2011-12) of approximately \$340 to \$1,400 for a number of minor applications which do not require an evaluation. Activities undertaken by the TGA for changes to product information involving an evaluation incur a fee of approximately \$4,500. The APVMA has fees (2011-12) of approximately \$500 to \$1,000 for a number of minor applications, for example, application for label change of a registered product.

The NICNAS activities associated with the Application to Vary Assessment Report and Application to Vary Full Public Report would be broadly comparable to the activities undertaken by the TGA for changes to product information involving an evaluation.

#### **B.1.4.3 Comparison of Annual Levies**

The NICNAS, TGA and APVMA each have an annual levy or registration charge. The annual levy or charge is necessary for each agency to satisfy its cost recovery obligations; for example, the NICNAS registration charge pays for the Existing Chemicals program, compliance activities, business management and corporate expenses.

APVMA registrants are required to pay levies based on the dollar value of sales (disposals) on each of their registered products. The levy rate is based on a percentage sliding scale beginning at 0.8 per cent of sales, decreasing to 0.3 per cent for higher dollar values. For example, for a sales value of \$3 million for a registered product, the first \$1 million of sales would be charged at 0.8 per cent and additional sales above this threshold would be charged at 0.45 per cent. The payable levy for a product with a sales value of \$3 million would be \$17,000 (2011-12).

The TGA annual charges are fixed, depending on the type of therapeutic good listed on the ARTG. There were approximately 62,600 products on the ARTG as at January 2011. Some of the TGA annual charges per product (2011-12) are listed below.

- Prescription medicines:
  - Annual charge - non-biologics: \$3,430
  - Annual charge - biologics: \$5,730
- Over-the-counter and complementary medicines:
  - Annual charge: \$1,170
- Listed medicines:
  - Annual charge: \$830

In comparison to both the APVMA and TGA, the NICNAS annual registration charge is based on the total value of individual chemicals imported or manufactured (introduced) each year, where the value is closely related to the customs value of each chemical. The charge is a fixed amount per company, depending on the total value of chemicals introduced. There are three levels or tiers of registration, with companies introducing chemicals of low total value paying a smaller fee. The charges (2011-12) are as follows:

- Tier 1 (introduction value \$1 to \$499,000): \$395

- Tier 2 (introduction value \$500,000 to \$4,999,999): \$1,577
- Tier 3 (introduction value \$5 million or greater): \$9,201

The APVMA levy is based on the value of products at the point of sale whereas NICNAS registration is based on the introduction value of individual chemicals. Industrial chemical products are not registered in Australia.

In comparing the TGA and NICNAS annual fees, it is noted that many industrial products contain multiple chemicals, for example, shampoo, lipstick, paint, ink. The TGA system if applied to industrial chemicals would be an unfair impost on companies introducing small volumes of products containing multiple chemicals as they would be charged per chemical, whereas other companies introducing a small number of chemicals in large volume would only pay for the individual chemicals, not by value or volume.

Using the APVMA approach NICNAS's financial viability would be dependent on the registration charges paid by a small group of companies and any movement in the status of these companies would significantly impact NICNAS revenue.

## ***B.2 INTERNATIONAL COMPARISONS***

The following information has been gathered from public sources.

### **B.2.1 European Chemicals Agency (ECHA)**

The mission of the European Chemicals Agency is to:

- Manage the regulation of industrial chemicals and Classification, Labelling and Packaging (CLP) tasks by carrying out or co-coordinating the necessary activities;
- Ensure a consistent implementation at EU level; and
- Provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals.

From 01 June 2007, the European Union Regulation on chemicals and their safe use (EC 1907/2006) makes no distinction between new and existing chemicals. Rather it is a legislation of **Registration**<sup>12</sup>, **Evaluation, Authorisation**<sup>13</sup> and **Restriction of Chemical substances (REACH)**. Existing chemicals are considered 'phase-in substances' and new chemicals are considered 'non phase-in substances'. The REACH pre-registration process allows the continued import/manufacture of phase-in substances prior to submitting a full registration dossier. Non phase-in substances don't benefit from pre-registration and need to submit a full registration dossier prior to import/manufacture.

The regulation requires that the assessments, to be carried out by industry, cover public health, occupational health and environmental components.

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<sup>12</sup> Registration in REACH means the submission by a manufacturer or importer of a technical dossier of information about a substance and, if the introduction volume is ten tonnes or more, a chemical safety report about the substance.

<sup>13</sup> Note: Under REACH substances of very high concern (SVHC) are determined by ECHA and an authorisation is required for their use and placement on the market.

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 €3,250). 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.

### **B.2.1.1 Comparison with NICNAS**

It is difficult to make direct comparisons with NICNAS due to the substantial differences between the two schemes and the way in which they have been set up. Under REACH the focus is more on existing substances and strategies to ensure control and safe use of chemicals of high health and/or environmental concern, e.g. authorisation of SVHC. Moreover ECHA is still a relatively new agency and steady baseline costs have not been established.

One of the major differences between REACH and NICNAS is that much of the assessment function is conducted by industry, with a relatively small proportion of chemical safety reports evaluated by ECHA. Therefore it is difficult to compare costs for the assessment or evaluation of a chemical substance.

Another major difference is that ECHA is required to manage an inventory of hazardous substances. In Australia this function is carried out by Safe Work Australia and is not a NICNAS function.

A similarity between the schemes is that cost concessions have been put in place for small business. Lower registration, authorisation and appeal fees have been introduced under REACH for SMEs. Similarly, NICNAS has lower assessment fees for the introduction of small volumes of chemicals, usually from smaller companies, and lower registration<sup>14</sup> charges for companies that introduce smaller amounts of chemicals.

Also both schemes have provision to apply costs for appeals. REACH has provision for fees and charges up to €6,600 to be applied for appeals against agency decisions. NICNAS has a small fee (\$737 (2011-12)) for applications to vary an assessment report; however, NICNAS has no fees for appeals to the Administrative Appeals Tribunal against a decision by the Director NICNAS.

### **B.2.2 Canadian Industrial Chemicals Scheme**

The *Canadian Environmental Protection Act (CEPA) 1999* prescribes the notification and assessment scheme for industrial chemicals in Canada. It includes the *New Substances Notification Regulations (NSNR)*. Similar to the *Industrial Chemicals Notification and Assessment Act 1989 (IC(NA) Act)*, *CEPA* provides criteria for identifying new substances (e.g., an inventory of existing chemicals), notification obligations for importers and manufacturers, a detailed chemical assessment mechanism and powers to implement specific controls. The purpose of NSNR is to ensure that no new substance is introduced into the Canadian market place before an assessment of its environmental and human

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<sup>14</sup> Note: Registration has different meanings under REACH and NICNAS – see B.2.1

health toxicity is made. Similar to the *IC(NA) Act*, the Canadian scheme has exemptions from notification, e.g., low volume chemicals.

Similar to the Australian Inventory of Chemicals Substances (AICS) administered by NICNAS, the Domestic Substances List (DSL) is the sole basis for determining whether a substance is new. Substances on the DSL are considered as existing substances and do not require notification, except for when a significant new activity (SNAc) is triggered.

Substances, other than animate products of biotechnology, which are not on the DSL but believed to be in international commercial use, are compiled in the non-Domestic Substances List (NDSL). The NDSL is based on the US Toxic Substances Control Act (TSCA) Inventory. Substances listed on the NDSL have reduced data requirements for notification and assessment.

#### **B.2.2.1 New Substances Program**

The Canadian New Substances Program includes risk assessment and risk management activities. The risk assessments cover human health (through Health Canada) and the environment (through Environment Canada). Unlike the *IC(NA) Act*, an occupational health and safety assessment is not within the scope of *CEPA*. The assessment period starts once all the required information is received by the New Substances program. Assessed new chemicals are added to the DSL 120 days following the determination that they are eligible. In 2008-09, approximately two per cent of the 492 new chemical notifications received required risk reduction activities.

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).

#### **B.2.2.2 Existing Chemicals program**

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). Substances were categorised on the basis of their potential for exposure to humans and the environment and on the basis of their potential persistence, bioaccumulation and toxicity (PBT).

The categorisation was a seven year endeavour in which two groups of 4-6 people each worked full time on the initiative. One group worked for Environment Canada performing toxicity assessments to address environmental concerns, while the other group worked for Health Canada performing toxicity assessments to address human health concerns. Neither the overall cost of this project, nor the breakdown of costs for this program is available. Expenses included contracting expertise, searching for data, as well as buying and developing predictive toxicity and exposure models. The modelling work was the major cost.

Following categorisation, risk assessment of prioritised chemicals was conducted under the Chemicals Management Plan (CMP)<sup>15</sup>. 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.

### **B.2.2.3 Comparison with NICNAS**

The Canadian assessment scheme is very similar to NICNAS except that cosmetics are not within the scope of the Canadian scheme and an occupational health and safety risk assessment is not conducted. Cost recovery arrangements, however, are quite different in Canada with only approximately 14 per cent of costs recovered from industry for new substances. Accordingly the fees in Canada for a new chemicals assessment are lower than NICNAS fees (C\$50 to C\$3,500 (2010-12) versus A\$2,841 to A\$16,782 (2011-12)).

The existing chemicals program is funded by government in Canada whereas under NICNAS, the existing chemicals assessment program is 100 per cent cost recovered through NICNAS registration fees.

Similar to NICNAS, Canada can reassess chemicals under their Significant New Activity (SNAc) provisions. However, no fee is charged in Canada. In NICNAS there is an assessment fee for the secondary notification of a chemical not on the inventory but no fee for the secondary notification assessment of an existing chemical.

Canada charges a fee for confidential searches of their inventory whereas NICNAS does not charge for bona fide searches of confidential AICS.

### **B.2.3 US Industrial Chemicals regulatory program**

The Environmental Protection Agency (EPA) regulates industrial chemicals in the USA to protect human health and the environment under the *Toxic Substances Control Act 1976 (TSCA)*. TSCA provides EPA with authority to require reporting, record-keeping and testing, and restrictions relating to chemical substances and/or mixtures. The EPA has broad authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures.

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<sup>15</sup> Note: The CMP included numerous non-industrial chemical activities such as evaluation of pesticides and management of food contaminants.

The Office of Pollution Prevention and Toxics (OPPT) manages programs under the *TSCA*. The EPA evaluates new and existing chemicals and their risks, and finds ways to prevent or reduce pollution before it gets into the environment. The *TSCA* Chemical Substances Inventory includes approximately 84,000 chemicals in commerce.

### **B.2.3.1 New chemicals 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. *TSCA* section 5 also requires a Significant New Use Notice (SNUN) from any person who proposes to manufacture, import or process a chemical for a use that is determined to be a ‘significant new use.’

Using notice information submitted to the agency, the EPA evaluates the health and environmental effects of new chemical substances. On the basis of its review, the EPA may take regulatory action with respect to the manufacture or importation of a new chemical substance or with respect to a substance’s proposed new use. At the EPA the average assessment time is 64 hours per PMN<sup>16</sup>, 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. The EPA requires that the submitter inform the EPA when non-exempt commercial manufacture, processing or importation of the substance in question actually begins by submitting a Notice of Commencement.

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 EPA assessments cover public health, occupational health and environmental assessments. Assessed new chemicals are added to the inventory when a notice of introduction is received from the company; however processing can take up to 4 weeks. 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<sup>17</sup>. 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.

### **B.2.3.2 Existing Chemicals program**

One of the EPA’s primary responsibilities under *TSCA* is to assess the safety of industrial chemicals, and address unreasonable risks posed by chemicals already in commerce. The Existing Chemicals

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<sup>16</sup> Source: “Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act”, December 11, 2007. Title: Premanufacturing Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances. EPA ICR No.: 0574.13. OMB Control No.: 2070-0012.

<sup>17</sup> Source: 2012 Justification of Appropriations for Committee on Appropriations, Fiscal Year 2012

program can be split into three major component activities: 1) strengthening chemical information collection, management, and transparency; 2) screening and assessing chemical risks; and 3) reducing chemical risks.

As noted above, 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 million<sup>7</sup> to assess chemicals, which will include developing hazard characterisations for 500 HPV chemicals and initiating detailed chemical risk assessments of priority chemicals.

### **B.2.3.3 Comparison with NICNAS**

Overall, the US notification and assessment scheme is similar to NICNAS except that no assessment report is published and cosmetics are not within the scope of the US scheme. The process of assessment for new chemicals is different to NICNAS in that a large proportion of assessments do not proceed to completion. Post assessment reporting obligations apply in the US where manufacturers and importers are required to provide information to the EPA every four years when their introduction volume is above the threshold of 25,000 lbs. The information reported includes production volumes, manufacturing sites and the manner in which the chemicals are used. Such post assessment obligations do not apply in Australia except annual reporting of chemicals used under exemption categories. It is therefore difficult to compare costs between the EPA and NICNAS, although it is noted that the mean cost of a PMN assessment is US\$5,265 (2007), within the range of NICNAS new chemicals assessments (A\$2,440 to A\$14,418 (2006-07)).

The average cost of a re-assessment (SNUN) under TSCA (US\$5,260 (2007)) is similar to the fee for a secondary notification under NICNAS (A\$3,451 to A\$7,985 (2006-07)). A SNUN is similar to the Canadian SNAc provisions and the NICNAS secondary notification obligations.

TSCA has a number of exemptions similar to those available under NICNAS. For example, the average cost for a LoREX (low volume low exposure) exemption available in the US is US\$2,160 (2007), similar to the NICNAS fee of A\$3,204 (2006-07) for a low volume permit.

Under TSCA a notice of commencement must be made to the US EPA, where in NICNAS no such notice is required. Also, in the US chemicals are listed on the inventory on notice of commencement whereas under NICNAS chemicals are automatically listed on the inventory after five years.

It is difficult to compare costs for the existing chemicals programs as the US program is in its early stages, with government funds provided for the program quite recently. Conversely, under NICNAS, the existing chemicals assessment program is 100 per cent cost recovered through NICNAS registration fees.

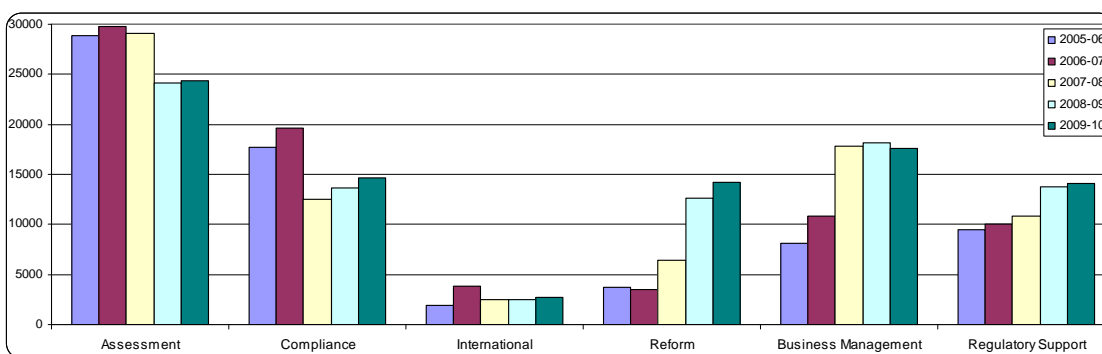
## APPENDIX C - TRENDS ANALYSIS

### C.1 Overview

The purpose of this section is to demonstrate trends in NICNAS regulatory activities during 2005-10, including total number of staff hours spent on those tasks.

Chart C1 shows the total staff hours spent on NICNAS activities for the past five years since the last CRIS. Activities are grouped into six distinct functions across the organisation. Each group is broken down into further detail in subsequent charts to demonstrate relevant trends.

**Chart C1: NICNAS staff hours by activity 2005-06 through 2009-10**



\*Assessment includes New and Existing Chemical assessments.

\* Compliance includes registration and auditing activities, and compliance-related stakeholder education and training.

\* Business Management includes activities that support business operations (e.g. property, administration, finance, IT, NICNAS database, and library).

\* Regulatory Support includes activities that support NICNAS' regulatory functions such as performance reporting, DoHA/TGA Corporate activities, ministerial correspondences, briefs and minutes related to programs, stakeholder education and outreach, enquiries, maintenance and management of the Australian Inventory of Chemical Substances (AICS), communications and committee support.

\* Externally funded projects and staff-related activities (leave, public holidays, training and development, performance management, recruitment and meetings) are excluded from Chart 1.

**Assessment** - The key points to note are that there was a decline in assessment activities in 2008-09 that coincided with the global financial crisis (GFC) resulting in a decrease in New Chemicals assessment applications (see chart C2). Internal reallocation of resources from Existing Chemical assessments to the Existing Chemicals Review Program (a reform activity) from 2007-08 onwards also contributed to the decrease in staff hours related to assessments and an increase in the reform effort.

**Compliance** – Mandatory registration of tier-1 registrants was introduced through amendments to the Industrial Chemicals (Notification and Assessment) Act (*IC(NA) Act*) in 2004-05 as a result of the Low Regulatory Concern Chemical (LRCC) reforms. The LRCC reforms also increased exemption volumes for some exemptions and introduced post-market annual reporting to balance the reduction in pre-market regulatory requirements. These changes necessitated an increase in education and outreach activities and this increase is reflected in the increase compliance hours in 2005-06 and 2006-07.

**International** – The effort spent on international harmonisation activities has been relatively stable over the past five years, with a slight spike in 2006-07. Further details are provided in chart C11.

**Reform** - There was an increase in the overall quantum of reform activities over this period, including cosmetics, disinfectants, Existing Chemicals program review, implementation of outstanding LRCC reforms, and nanotechnology. Refer to charts C12-C15 for further details.

**Business management** – Total hours spent on business management activities increased significantly in 2007-08 due to NICNAS taking on financial management activities that were previously undertaken by the TGA on behalf of NICNAS (NICNAS was under the TGA Group of Regulators until 2007-08). The time spent on business management activities has remained relatively steady since 2007-08.

**Regulatory support** – This work has steadily increased due to an increased focus on communication activities, including training, stakeholder outreach and a significantly increased effort required to support consultative committees advising on regulatory reforms. See charts C21 and C22 for further details on committees.

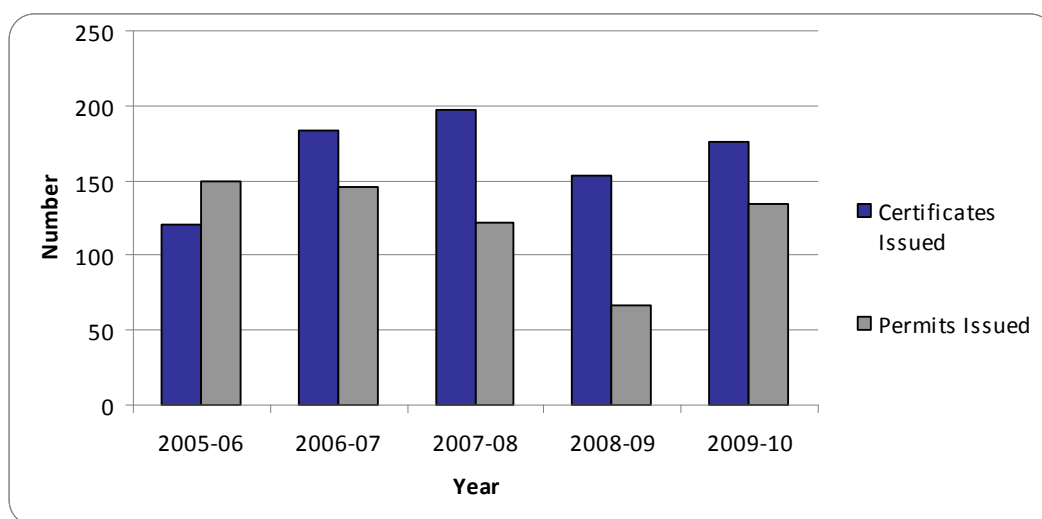
## C.2 Assessments

### C.2.1 New Chemicals

New Chemical assessments are funded on a fee for service basis. The following charts outline trends in New Chemical assessment activity in terms of the number of certificates and permits issued from 2005-06 to 2009-10.

Taken together, these trends demonstrate a decline in applications in 2008-09, a direct implication of the GFC. However they also demonstrate a recovery in 2009-10 with a return to approximately pre 2008-09 levels (Chart C2).

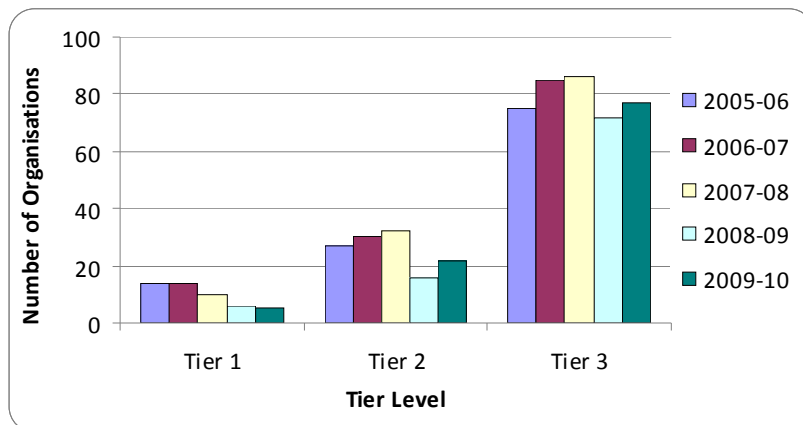
**Chart C2: New Chemical assessments issued 2005-06 through 2009-10**



The total number of companies notifying New Chemicals is relatively constant across the five years. The majority of New Chemical assessment certificate and permit applications are from tier-3 registrants. Approximately 20 per cent are from tier-2 registrants, with only 5-10 per cent from tier-1

registrants (Chart C3). The number of tier-2 and tier-3 companies notifying New Chemicals declined in 2008-09, which was a direct reflection of the GFC.

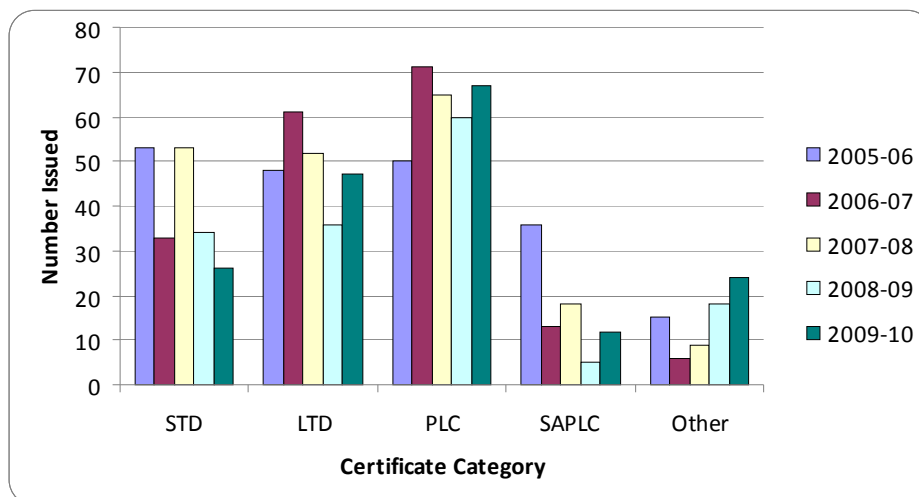
**Chart C3: Notifying companies by registration tier level 2005-06 through 2009-10**



Over 75 per cent of all New Chemicals certificates issued are in Standard (STD), Limited (LTD) or Polymer of Low Concern (PLC) categories (Chart C4). Since 2006-07, use of the PLC category has been significant and relatively stable (60 - 71 per year). The number of LTD certificates issued is generally higher than the number of STD certificates in each year. This is attributed to less data requirements and lower fee of the LTD certificate.

A range of lower cost LRCC notification categories were introduced in 2004-05. This change is reflected in an increase in usage of 'Other' categories since 2006-07 (Chart C4). Self Assessed PLCs (SAPLCs) were introduced as an LRCC category in 2004-05. While this category enables industry to undertake a self assessment of their chemical, it also requires compulsory annual reporting by industry. As part of NICNAS' compliance program, 100 per cent of self assessed applications were audited in the first year of implementation (2005-06) and use of the SAPLC category has been lower since that time (Chart C4).

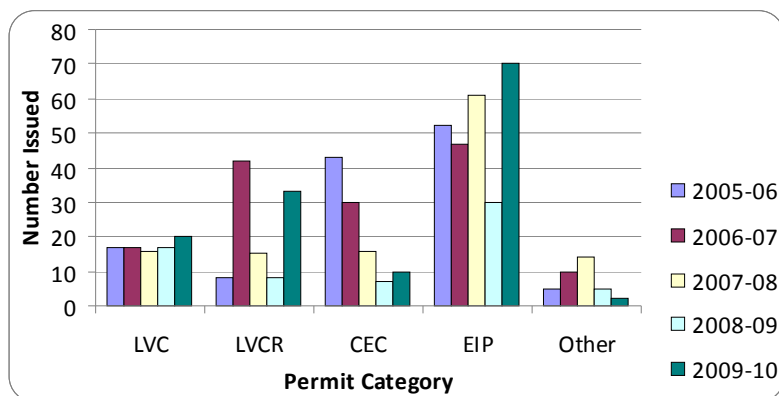
**Chart C4: Breakdown of New Chemical certificates issued 2005-06 through 2009-10**



\*'Other' includes SANHP, SANHC, EX, SN, STD-FS, STD-Mod, STD-Fam, LTD-FS, LTD-Mod, LTD-Fam, PLC-FS and PLC-Mod.

The number of Low Volume Chemical (LVC) permits issued has been stable during 2005-10, but since the introduction of LRCC exemption categories, a steady decline in the use of Commercial Evaluation Category (CEC) permits was observed (Chart C5). Early Introduction Permits (EIPs) are linked to a certificate application and their use has increased over the last five years, except during the GFC when certificate applications dropped. NICNAS commenced issuance of free EIPs midway through 2008-09 under specific conditions. No consistent trend is observed in low volume chemical permit renewals (LVCR).

**Chart C5: Breakdown of New Chemical permits issued 2005-06 through 2009-10**



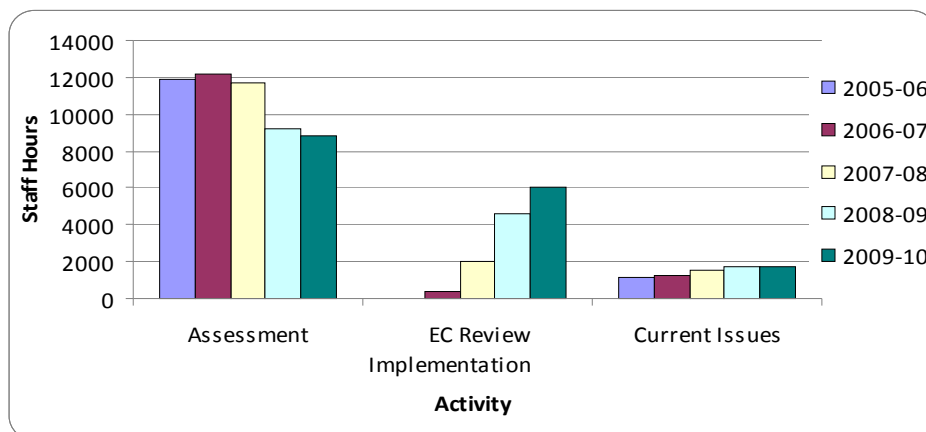
\*'Other' includes CECR, EOP and EOPR

### C.2.2 Existing Chemicals

Activities relating to Existing Chemicals are funded from the NICNAS registration levy. NICNAS completed a review of its Existing Chemicals Program in December 2006 and published an implementation plan in July 2007.

Chart C6 demonstrates a decrease in time spent on Existing Chemicals assessments as resources were gradually re-allocated to implementing recommendations from the Existing Chemicals review, in particular a shift to focus on recommendations relevant to screening and prioritising Existing Chemicals (see section C.5).

**Chart C6: Existing Chemicals staff hours versus activities 2005-06 through 2009-10**



\*Management and administrative activities, national and international engagements have not been included in this chart.

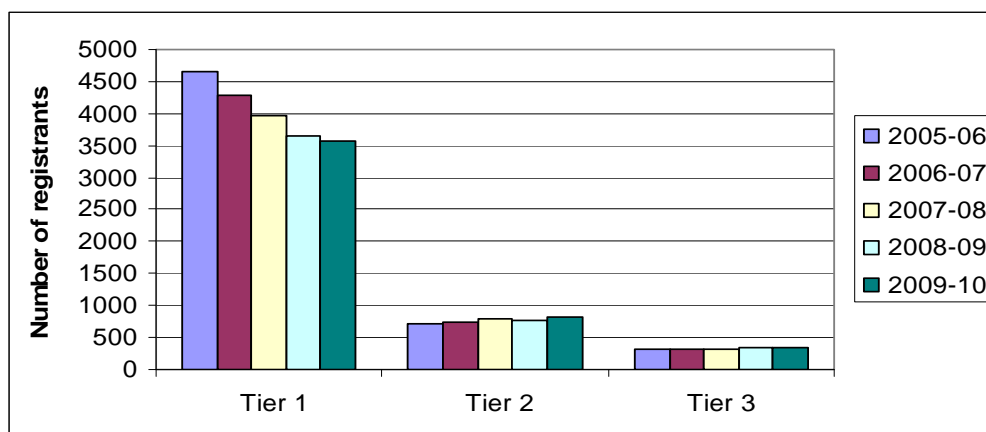
### C.3 Compliance

NICNAS compliance activities are funded from the NICNAS registration levy and include seven major groups of activities: processing new registrations and yearly registration renewals, auditing and monitoring, international treaties, partnerships with external agencies, investigations and management of breaches of the *IC(NA) Act*, and stakeholder education programs.

#### C.3.1 NICNAS registration

Chart C7 demonstrates trends in registrant numbers. Tier-1 registration was introduced through the LRCC reforms in 2004-05 and numbers have steadily declined over the years. The decline is assumed to be due to a combination of factors including change in tiers, a decline in overall number of registrations due to GFC-related downturn, and changes in business practices, including by those involved in very small volume imports. The numbers of tier-2 and tier-3 registrants has remained relatively constant.

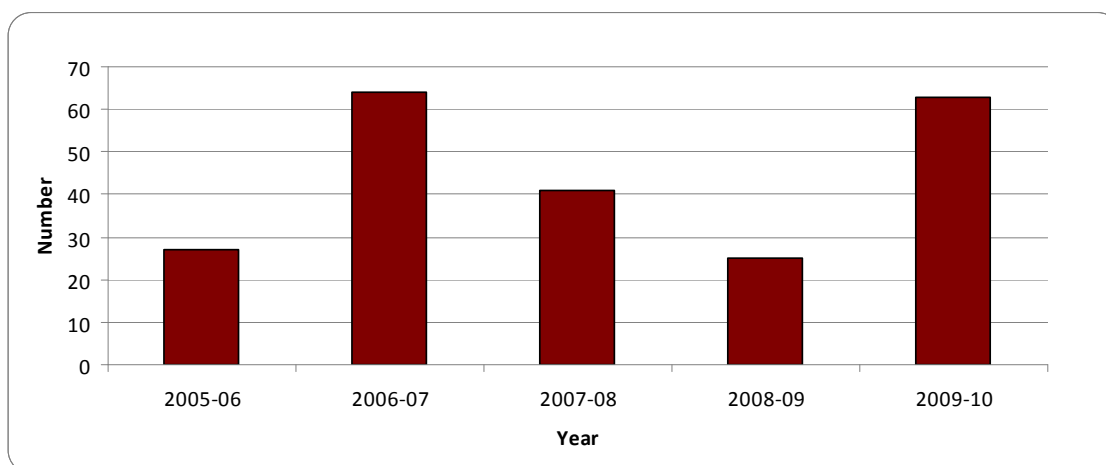
**Chart C7 - Current registrants 2005-06 through 2009-10**



### C.3.2 Compliance investigations

The rise in number of investigations completed in 2006-07 reflects an increase in auditing of annual reports for chemicals being introduced under exemption categories (Chart C8). The decrease in the number of investigations in 2007-08 and 2008-09 reflects effort being diverted to other issues, for example, administration and handling of NICNAS registrations. Investigations increased again in 2009-10 due to increased audit activity on cosmetics and company registrations.

**Chart C8 – Investigations\* completed 2005-06 through 2009-10**



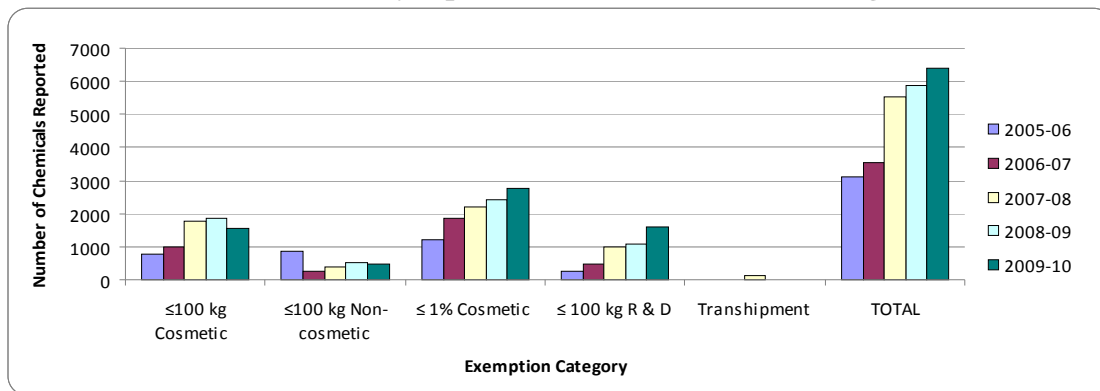
\* Investigation is case management of an identified or potential non-compliance.

### C.3.3 Annual reporting

Annual reporting of chemicals used under exemption categories, permits and self-assessed certificate categories was introduced in 2004-05 as part of the LRCC reforms. Chart C9 demonstrates the number of chemicals reported as being introduced under each exemption category. In general, the number of chemicals introduced under exemptions has increased significantly overtime. The significant overall

increase in 2007-08 and 2008-09 is attributed to increased follow-up activities with businesses to ensure compliance with annual reporting requirements. It is evident that the transshipment exemption category is under-utilised. NICNAS plans to revise conditions under which this exemption can be used in the future.

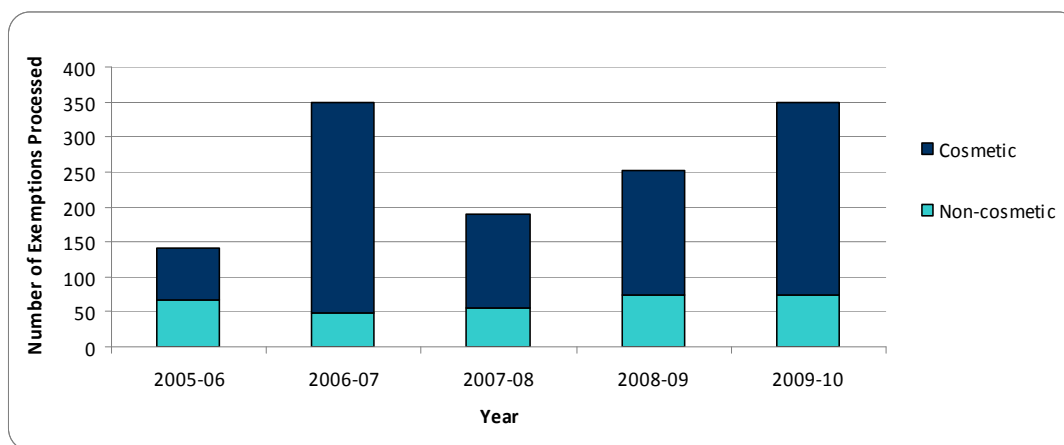
**Chart C9 – Number of annually reported chemicals\* 2005-06 through 2009-10**



\* Chemicals introduced under exemption categories in a registration year and reported to NICNAS the following year.

Introducers of chemicals under certain exemption categories (e.g. cosmetic chemicals introduced between 10 and 100 kg per year) are required to advise NICNAS prior to trading in that chemical. NICNAS processes the receipt of these advice forms and provides written confirmation of its receipt to the introducer. This confirmation may also advise the introducer if the chemical has been identified as being unsuitable for introduction under the exemption provisions (Chart C10). The large spike in 2006-07 is attributed to the introduction of cosmetic reforms and subsequent issue of interim permits for chemicals used as ingredients in products that transferred from TGA to NICNAS for regulation as cosmetics. To a lesser extent, this increase may also be a result of delayed uptake of new exemption provisions and increased volume thresholds to existing provisions which were introduced in 2004-05.

**Chart C10 – Number of exemption advices processed 2005-06 through 2009-10**



The number of cosmetic exemptions is increasing significantly. NICNAS aims to reduce the reporting burden on business by implementing a mechanism for online submission of exemption advice which

will result in improved efficiencies of processing by NICNAS, and a rapid acknowledgement of the advice to the introducer. The online system is planned for 2012-13.

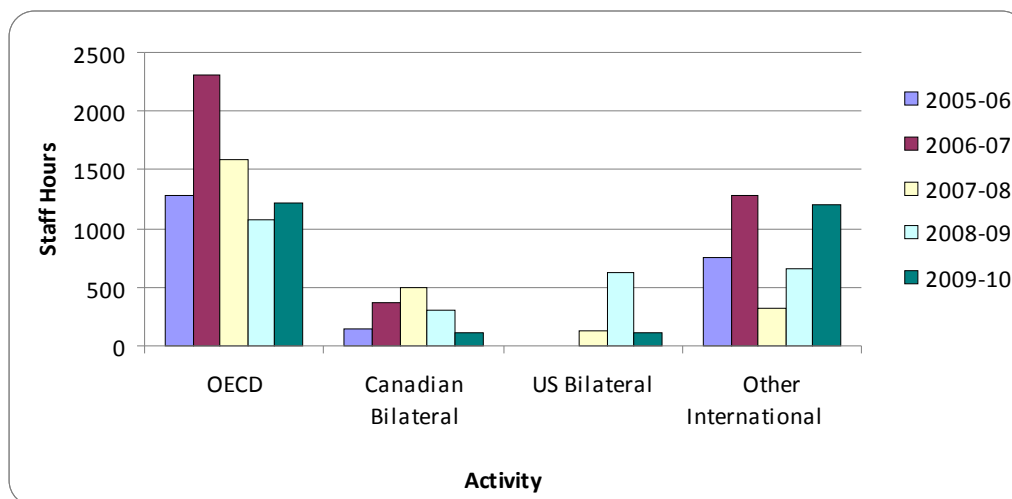
### C.4 International Activities

NICNAS utilizes bilateral and multilateral engagement to progress its international harmonization efforts and reduce duplication of effort. Chart C11 demonstrates the overall effort expended on international activities.

OECD activities included the review of chemicals under the OECD Cooperative Chemicals Assessment Program (formerly the High Production Volume Chemicals Program), which provided benefits by reducing duplication of effort through international data-sharing. There was relatively constant effort on OECD activities over the period, except in 2006-07, where increased effort was spent on identifying perfluorinated chemicals in use nationally and internationally. This work resulted in an OECD publication and informed NICNAS of perfluoro-chemicals actually in use in Australia.

Establishment of bilateral agreements is resource intensive while their ongoing maintenance requires significantly less effort. Increased effort is demonstrated in 2007-08 for the Canadian bilateral (renewed in 2007) and in 2008-09 for the US bilateral (signed in 2008).

**Chart C11 – Staff hours spent on activities associated with international engagement**



\*Other international includes PIC, POP, APEC, IPCS.

### C.5 Reform

NICNAS has engaged in a range of reform activities in the period 2005-06 to 2009-10. These include: the review of its Existing Chemicals Program, Low Regulatory Concern Chemicals Reforms including cosmetics reforms, a review of the regulation of industrial nanomaterials and disinfectants.

Chart C12 shows that effort expended on activities related to implementing recommendations from the review of the Existing Chemicals program increased from 2007-08 through to 2009-10. A sharp increase in staff time devoted to cosmetics reforms in 2006-07 was related to the administration of the

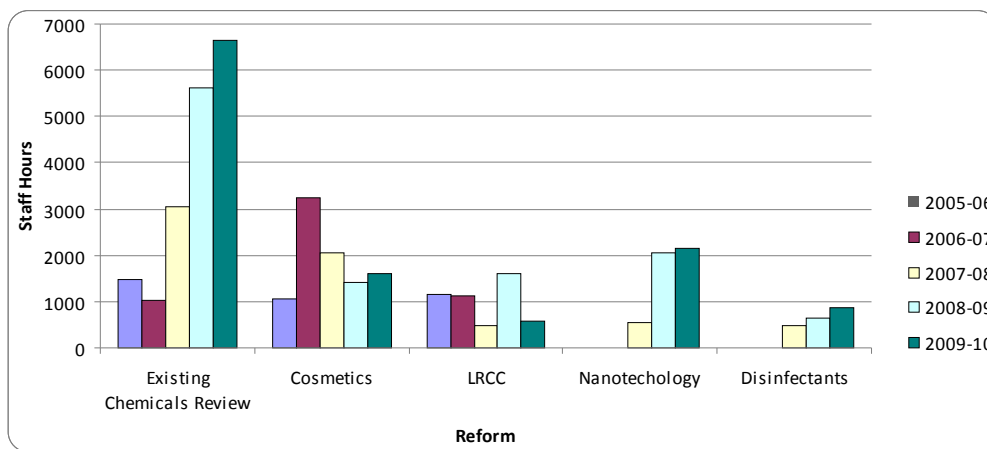
cosmetic interim arrangements to recognise certain product categories as cosmetics within the NICNAS framework, ahead of legislative arrangements.

Time spent on LRCC reforms was fairly stable although there was a peak in 2008-09. This coincided with implementation of the outstanding LRCC reforms, particularly around New Chemical notification and assessment categories and commencement of an evaluation of the first stage of the reforms.

Nanotechnology and disinfectant reforms commenced in 2007-08, (Chart C12). Significant effort has been expended on nanotechnology reforms with contributions from the Government’s National Nanotechnology Strategy and its successor, the National Enabling Technology Strategy. This work included a review of NICNAS’s regulatory processes and practices to determine their suitability to regulate this novel technology and the establishment of a multi-stakeholder advisory group, the Nanotechnology Advisory Group. NICNAS’s nanotechnology reforms are ongoing.

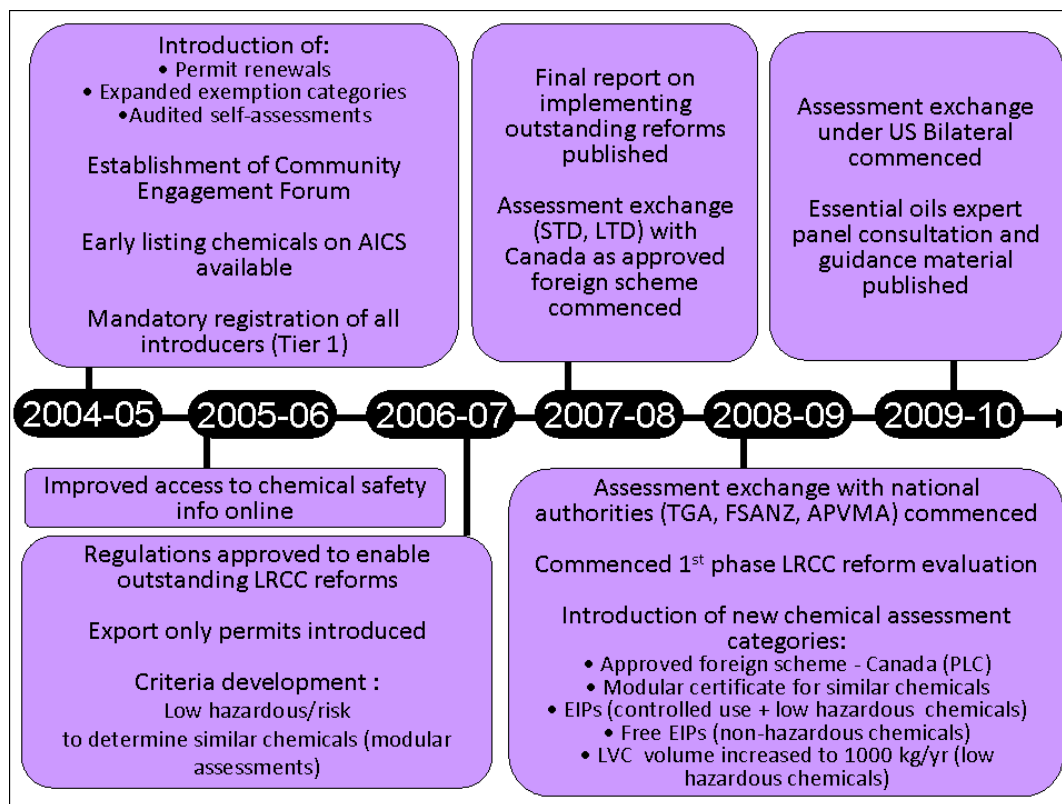
An examination of current regulatory arrangements for disinfectants commenced in 2007-08 and progressed in consultation with the TGA and DoHA. NICNAS currently awaits the outcome of consideration of regulatory arrangements within the TGA for the regulation of disinfectant products.

**Chart C12 - Hours spent on Reform activities – All NICNAS Staff**

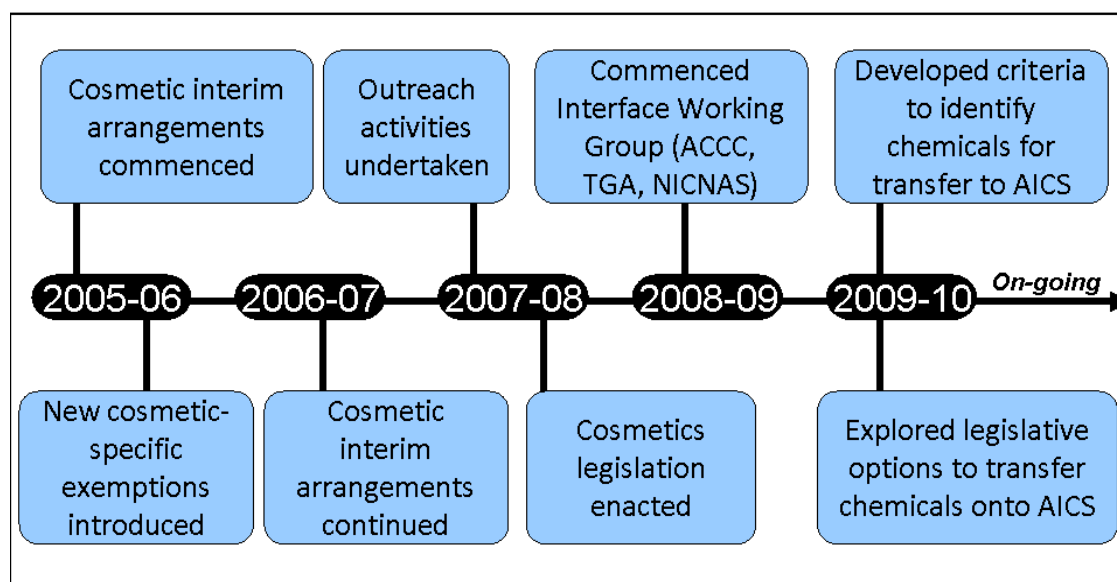


Charts C13 - C15 detail outputs from LRCC, cosmetic reforms and the Existing Chemicals review. These demonstrate the length of time required to explore and develop options for reform, consult with stakeholders and fully implement a significant reform program.

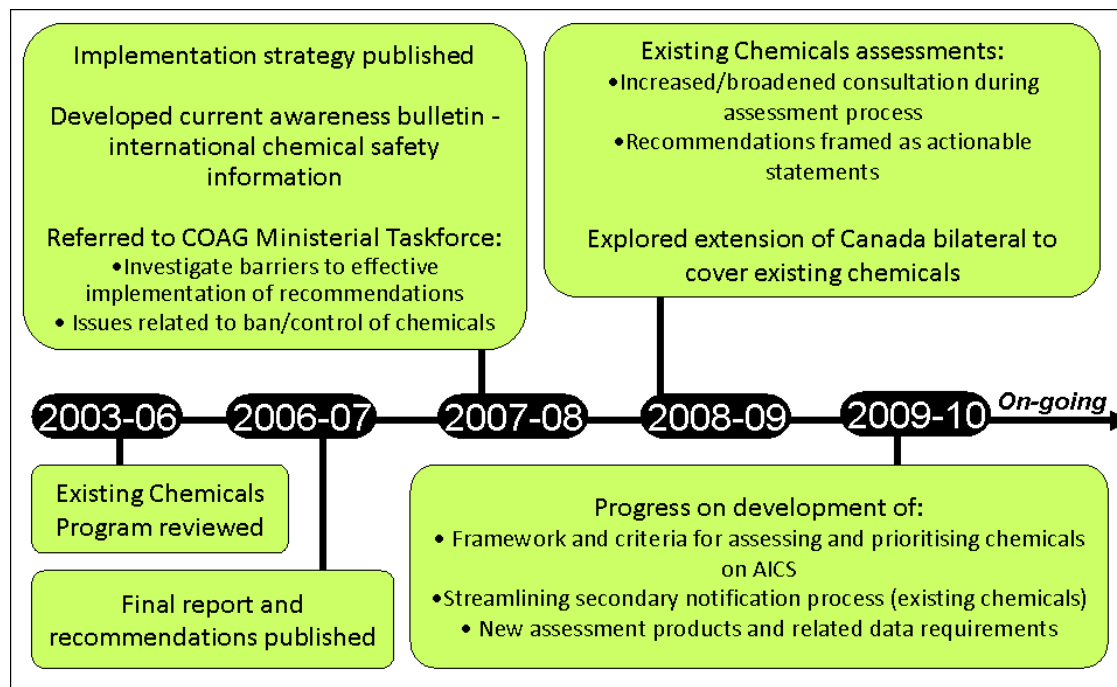
**Chart C13 – Roll out of LRCC reforms**



**Chart C14 – Roll out of cosmetic reforms**



**Chart C15 – Roll out of Existing Chemicals Program Review\***



\*Refer to chart C22 for establishment of advisory bodies and expert groups.

### **C.6 Business Management**

As an independent business unit, NICNAS has enhanced its business operations over time.

Chart C16 shows activities and processes that have contributed to efficiencies in business operations. Improvements in finance and reporting includes streamlined NICNAS registrations and debt recovery processes, proactive business risk identification and mitigation plans, and enhanced internal and external accountability and reporting arrangements.

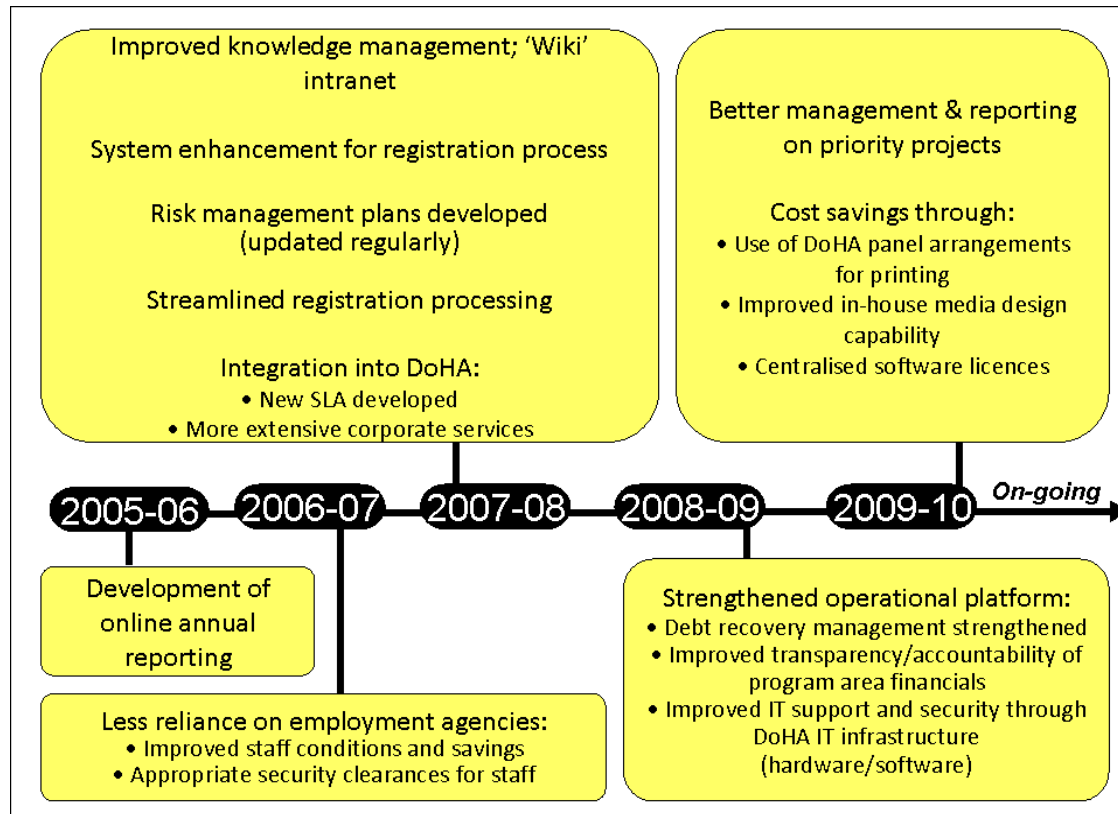
Efficiencies in IT infrastructure and security were achieved through migration to DoHA desktops and servers in early 2009. Specifically NICNAS now benefits from improved IT security management and conformance to the Government's IT security guidelines through the DoHA dedicated team of IT security experts. There is also a lower risk of IT failure through regular maintenance and early detection of issues

While under the TGA Group of Regulators, NICNAS obtained some services from DoHA on a fee-for-service basis. Integration into the department in 2007-08 afforded access to a greater range of corporate services delivered through a renewed service-level agreement (SLA).

Other activities that resulted in cost-savings or increased productivity include changes to financial approval processes, use of procurement panels and regular internal audits of NICNAS compliance

with DoHA procedures and the Government financial management regulations (*Financial Management and Accountability Act 1997*).

**Chart C16 – Business efficiency measures from 2005-06 to 2009-10**



### C.7 Regulatory Support

Several NICNAS activities directly support its regulatory functions. The more significant activities are maintenance and management of the AICS, stakeholder education and outreach activities, the NICNAS website, responding to inquiries from industry, community and governments and committee support for NICNAS's non-statutory and advisory committees.

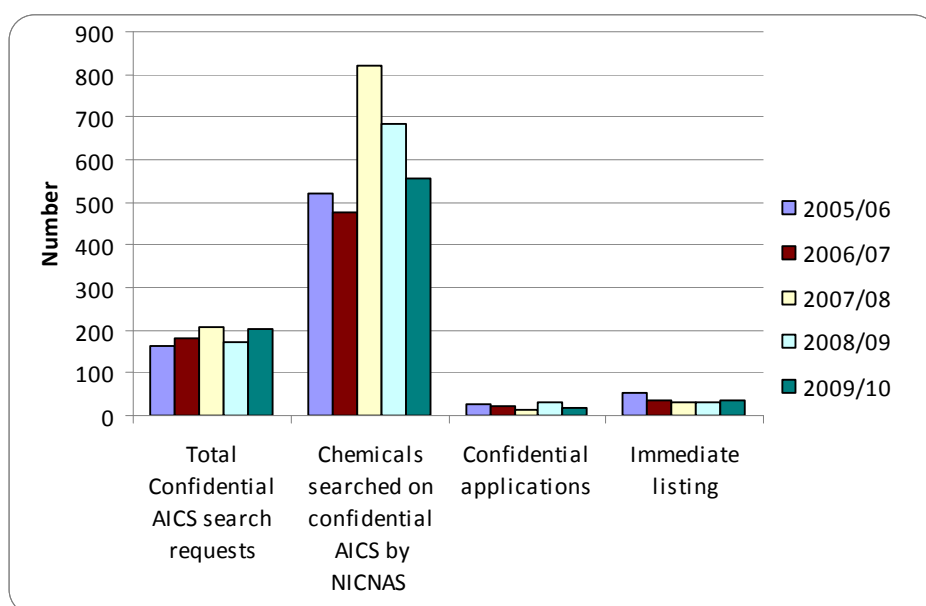
#### C.7.1 The Australian Inventory of Chemical Substances

The public AICS is available online and stakeholders can search for chemicals themselves. The confidential section of the inventory can only be searched by NICNAS on receipt of a search request and confirmation of bona-fide intent to introduce the chemical for which a confidential search has been requested. A confidential search request can include one or more chemicals. Chart C17 shows that AICS-related activities remained relatively steady over 2005-10, although there was a surge in the number of AICS searches for chemicals by NICNAS on behalf of customers during 2007-08. This is related to the roll-out of the cosmetic interim arrangements, which was associated with a large increase in the number of businesses requesting searches of the confidential inventory to ascertain whether certain affected chemicals were eligible for participation in the interim arrangements.

Following the issuance of a New Chemicals assessment certificate, a chemical is listed on AICS after a 5-year period unless the applicant requests that it be listed immediately; immediate listing is on the public AICS. Chart C17 demonstrates a small but consistent number of requests for immediate listing on the inventory.

Following a 5-year period the applicant to the New Chemical assessment can request that the chemical be listed on the confidential section of the inventory and not the public inventory. NICNAS uses a transparent process to determine eligibility for listing on the confidential inventory and obtains advice from an external technical Advisory Group in determining whether or not to grant confidential listing. Chart C17 demonstrates the small yet consistent volume of requests for listing chemicals on the confidential inventory.

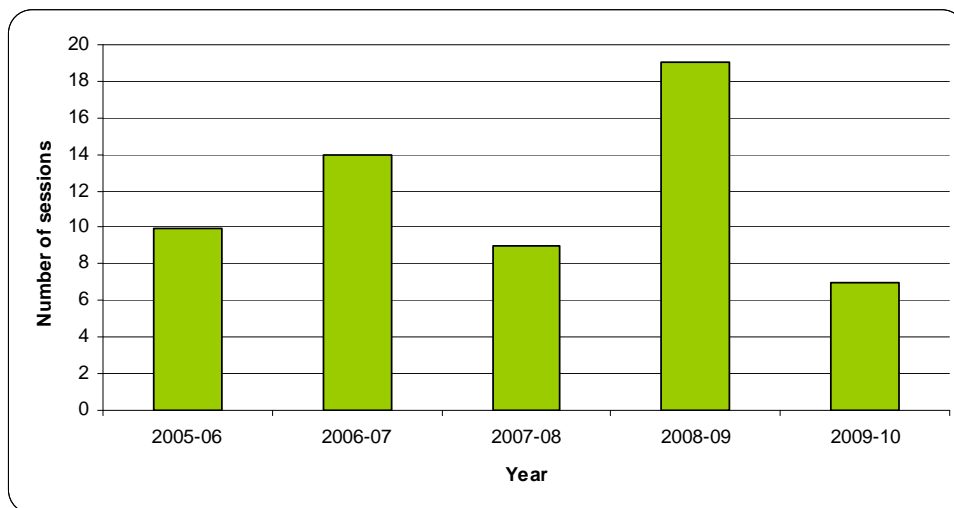
**Chart C17 – AICS related activities**



**C.7.2 Stakeholder education and outreach**

The number of industry education and outreach sessions was relatively steady from 2005 to 2010 (Chart C18), although there was an increase in 2006-07 due to additional training seminars held on the cosmetic interim arrangements. In 2008-09, there was another rise in the number of outreach activities as a result of high levels of interest from industry for NICNAS compliance training and additional training seminars held on the new LRCC categories.

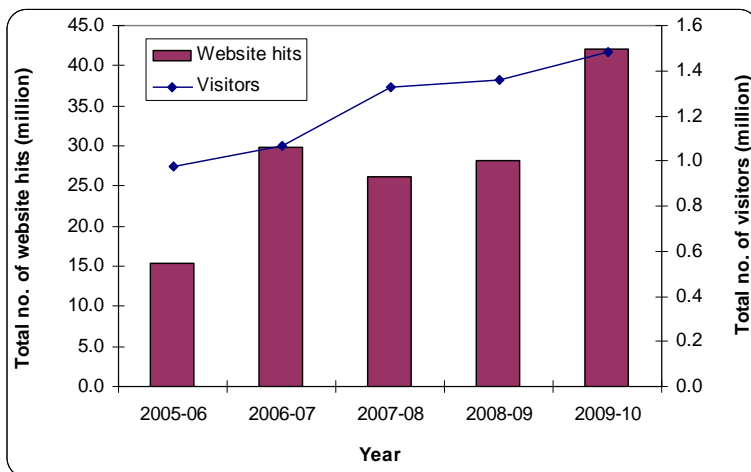
**Chart C18– Stakeholder information and education sessions held from 2005-06 through 2009-10**



### C.7.3 NICNAS website

Use of the NICNAS website has generally risen during 2005-10, with the total number of website hits reaching more than 42 million in 2009-10 (Chart C19). This was associated with an overall rise in the number of website visitors. The increase is likely to be due to increased delivery of online information and downloadable forms (e.g. applications for new chemical notifications, registrations), making the website a prime information tool for users.

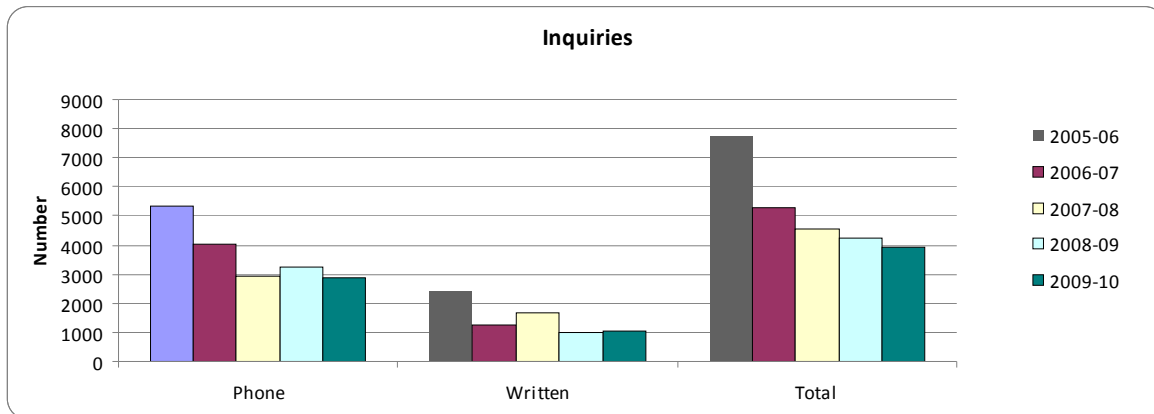
**Chart C19: Number of hits on the NICNAS website and visitors**



### C.7.4 Inquiries

Chart C20 shows that overall, the number of phone and written inquiries declined over time, presumably due to greater availability of information on the NICNAS website and increased emphasis on stakeholder education and outreach activities. The high number of inquiries in 2005-06 was a direct result of the introduction of tier-1 registration and late penalty fees for NICNAS registration.

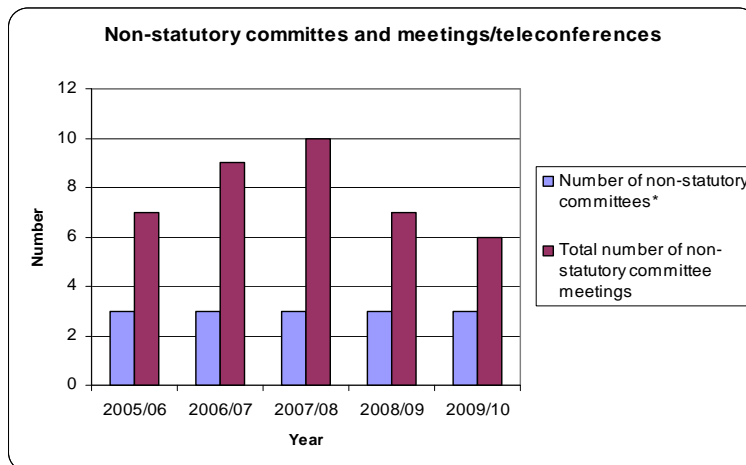
**Chart C20: Number of inquiries handled by NICNAS 2005-06 through 2009-10**



### C.7.5 NICNAS committees

Non-statutory committees are long-standing and continuing committees with regular scheduled meetings. The total number of meetings from 2009-10 was lower due to a decrease in the number of MoU committee meetings (Chart C21).

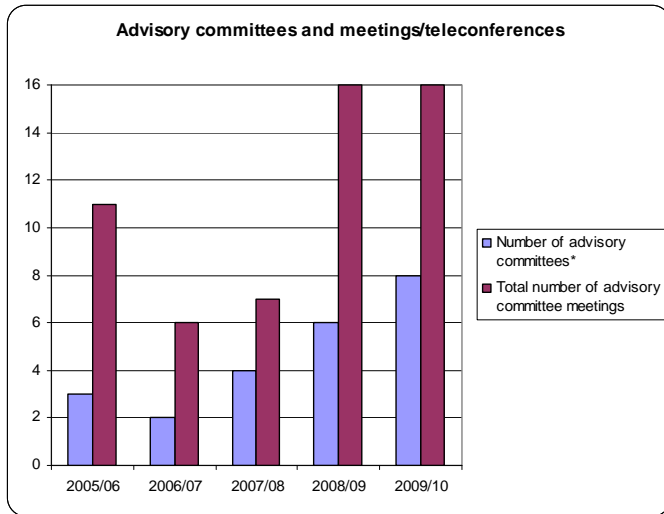
**Chart C21: Number of NICNAS non-statutory committees and number of meetings held 2005-10**



\*IGCC, CEF, MoU.

Advisory committees relate to specific projects/activities that are undertaken by NICNAS, therefore there are often variations in the number of committees and the number of meetings held in a given period. The total number of advisory committees and associated meetings increased from 2007-08 due to an increase in reform activities around cosmetics, nanotechnology and the review of the Existing Chemicals Program (Chart C22).

**Chart C22: Number of NICNAS advisory committees (project/activity-specific committees) and number of meetings held 2005-06 through 2009-10**



\*Cosmetic Advisory Group (CAG), Nanotechnology Advisory Group (NAG), Stream 2 Technical Working Party (S2 TWP), Industry Engagement Group (IEG), Implementation Steering Group (ISG), Environmental Expert Working Group, Human Health Expert Working Group, and Technical Advisory Group (TAG).

**APPENDIX D - ANNUAL LEVY ANALYSIS**

While generating the options analysis several possible models were created. Some of the structures that were modelled, and subsequently discounted, are identified below.

Note, the number of registrants in each tier and the total cost to be recovered correspond to period of ABC study (1 April 2009 to 31 March 2010).

***D.1 Charge all introducers an equal percentage of the introduction value***

One option is to charge all introducers an equal percentage of their introduction value. The resulting charge would equal 0.024 percent of a registrant's introduction value in order for NICNAS to recover its full costs. This results in the maximum fee payable (that is for the organisation that introduces the greatest value) of approximately \$1.18m per annum, while approximately 600 introducers would be charged less than \$1, and a further 2,550 (approximately) would be charged less than the administrative costs associated with their annual registration (that is, less than \$112).

Approximately 350 NICNAS registrants introduce chemicals at a value of greater than 5 million per annum and 20 companies at an introduction value of greater than 100 million. If a flat levy approach were to be adopted, NICNAS's financial viability would be dependent on the registration charge to be paid by a small group of companies and any movement in the status of these companies (e.g., merger, insolvency) would significantly impact NICNAS revenue.

In conclusion, a flat levy system would result in a dramatic increase in fees for large introducers, an increased administrative impost on NICNAS, and a potential threat to the financial stability of NICNAS. Therefore, this option would not present an efficient and cost effective framework for NICNAS registration.

***D.2 Match tier-1 fee to current administrative cost, correct inequity in charging and introduce a higher tier (introduction value > \$50 million)***

One option is to adjust the tier-1 fee to reflect the current administrative costs (as determined through the ABC study), make the maximum payable amount (as a proportion of introduction value) the same for tiers-2 and -3, while also introducing a fourth tier for organisations that introduce more than \$50 million in relevant chemicals. The table below shows the charges that would result, with the cost as a percent of minimum introduction value and total amount recovered by tier also presented.

**Table D1: Second model for annual fees and charges**

Tier	Applicable Introduction Value	Registration Fee and Charge	Approximate Number of Companies	Cost as per cent of minimum introduction value	Total amount recovered
1	\$1 - \$499,999	\$112	3,481	n/a	\$389,872
2	\$500,000 - \$4,999,999	\$630	921	0.13%	\$580,230
3	\$5,000,000 - \$49,999,999	\$6,300	314	0.13%	\$1,978,200
4	\$50,000,000 or more	\$63,000	52	0.13%	\$3,276,000
					<b>\$6,224,302</b>

***D.3 Match tier-1 fee to current administrative cost, correct inequity in charging, adjust the thresholds for tier-2 and -3, and introduce two higher tiers (introduction value >\$10 million and >\$50 million)***

Adjust tier-1 to reflect the current administrative costs (as determined through this study) and make the maximum payable amount (as a proportion of introduction value) the same for all tiers, while adjusting the thresholds for tiers-2 and -3 and introducing higher tiers with introduction values \$10,000,000 - \$49,999,999 and >\$50,000,000. The result is the following fees, with the cost as a percent of minimum introduction value and total amount recovered by tier also presented.

**Table D2: Third model for annual fees and charges**

Tier	Applicable Introduction Value	Registration Fee and Charge	Approximate Number of Companies	Cost as per cent of minimum introduction value	Total amount recovered
1	\$1 - \$499,999	\$112	3,481	n/a	\$389,872
2	\$500,000 - \$1,499,999	\$530	536	0.11%	\$284,080
3	\$1,500,000 - \$10,000,000	\$1,590	510	0.11%	\$810,900
4	\$10,000,000 - \$49,999,999	\$10,600	189	0.11%	\$2,003,400
5	\$50,000,000 or more	\$53,000	52	0.11%	\$2,756,000
					<b>\$6,244,252</b>

***D.4 Match tier-1 fee to current administrative cost, correct inequity in charging, adjust the thresholds for tier-1, -2 and -3, and introduce two higher tiers (introduction value >\$10 million and >\$50 million)***

The fourth option assessed was the same as option three only with a reduced maximum value for tier-1 (to \$250,000). This resulted in the following fees, with the cost as a percentage of minimum introduction value and total amount recovered by tier also presented.

**Table D3: Fourth model for annual fees and charges**

Tier	Applicable Introduction Value	Registration Fee and Charge	Approximate Number of Companies	Cost as per cent of minimum introduction value	Total amount recovered
1	\$1 - \$249,999	\$112	3,171	n/a	\$355,152
2	\$250,000 - \$1,499,999	\$270	845	0.11%	\$228,150
3	\$1,500,000 - \$10,000,000	\$1,620	510	0.11%	\$826,200
4	\$10,000,000 - \$49,999,999	\$10,800	189	0.11%	\$2,041,200
5	\$50,000,000 or more	\$54,000	52	0.11%	\$2,808,000
					<b>\$6,258,702</b>

***D.5 Match tier 1 fee to current administrative cost, correct inequity in charging, adjusting the thresholds for tiers 1, 2 and 3, and introduce three higher tiers (introduction value >\$10 million, >\$30 million, and >\$50 million)***

The fifth option took the fourth model and added two additional tiers (by separating tiers-2 and -4 into two each).

**Table D4 – Fifth model for annual fees and charges**

Tier	Applicable Introduction Value	Registration Fee and Charge	Approximate Number of Companies	Cost as a percent of minimum introduction value	Total amount recovered
1	\$1 - \$249,999	\$112	3,171	n/a	\$355,152
2	\$250,000 - \$499,999	\$235	310	0.09%	\$72,850
3	\$500,000 - \$1,499,999	\$470	536	0.09%	\$251,920
4	\$1,500,000 - \$9,999,999	\$1,410	510	0.09%	\$719,100
5	\$10,000,000 - \$29,999,999	\$9,400	155	0.09%	\$1,457,000
6	\$30,000,000 - \$49,999,999	\$28,200	34	0.09%	\$958,800
7	\$50,000,000 or more	\$47,000	52	0.09%	\$2,444,000
					<b>\$6,258,822</b>

***D.6 Match tier-1 fee to current administrative cost, correct inequity in charging, and splitting tier-1 into two***

The preferred option involved creating four tiers, splitting the current tier-1 into two. This model results from the reduced cost of the administrative aspects of the annual registration process, coupled with the desire to increase the number of introducers making a contribution to post market activities.

A summary of the charges under this scenario for the period of the activity based costing study is presented in the table below.

**Table D5 – Registration fee and charge required to fully cost recover based on proposed 4-tier structure**

Tier	Applicable Introduction Value	Registration Fee and Charge	Approximate Number of Companies	Cost as per cent of minimum introduction value	Total amount recovered
1	\$1 - \$99,999	\$112	2,724	n/a	\$305,088
2	\$100,000 - \$499,999	\$250	757	0.25%	\$189,250
3	\$500,000 - \$5,000,000	\$1,250	921	0.25%	\$1,151,250
4	\$5,000,000 or more	\$12,500	366	0.25%	\$4,575,000
					<b><u>\$6,220,588</u></b>

There are three key reasons behind this being chosen as the preferred model:

- Ensuring the direct costs associated with the annual registration process are covered by the annual charges;
- More than 4,000 of the introducers will pay less than what they are currently paying while less than 370 introducers will pay more; and
- Reduces the number of registrants paying more than 100% of the introduction value from 94 to 42.