



Australian Government

Department of Health and Ageing
NICNAS

NICNAS Cost Recovery Impact Statement

Discussion Paper

June 2010

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Glossary of Terms and Abbreviations

ABS – Australian Bureau of Statistics

AICS - Australian Inventory of Chemical Substances

CAC Act - Commonwealth Authorities and Companies Act 1997

CPI – Consumer Price Index

COAG – Council of Australian Governments

Cost Recovery Guidelines - Australian Government Cost Recovery Guidelines (available online at http://www.finance.gov.au/publications/finance-circulars/2005/09.html#FMG_4)

CRIS – Cost Recovery Impact Statement. A statement documenting compliance with the Australian Government cost recovery policy.

DoFD – Department of Finance and Deregulation

DoHA – Department of Health and Ageing

EU – European Union

FMA Act - Management and Accountability Act 1997

IC(NA) Act - Industrial Chemicals (Notification and Assessment) Act 1989

IGCC - Industry Government Governance Committee

NICNAS - National Industrial Chemicals Notification and Assessment Scheme

PC – Productivity Commission

PC report – Productivity Commission, *Chemicals and Plastics Regulation*, Research Report, 2008 (available online at <http://www.pc.gov.au/projects/study/chemicalsandplastics>)

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

WPI – ABS Wage Price Index

Purpose

The purpose of this document is to present information for stakeholder consideration and to invite feedback on issues to be included in the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Cost Recovery Impact Statement (CRIS). Feedback received will be duly considered in the development of the CRIS.

The objectives of this consultation are to:

- identify and understand any issues with the current cost recovery framework;
- obtain a clear understanding of how NICNAS activities have changed since the last CRIS in 2004-05;
- prioritise the major issues of stakeholder concern regarding the efficiency and effectiveness of NICNAS operations; and
- explore mechanisms to cost recover the implementation of recommendation 4.6 of the Productivity Commission (PC) report.

A series of questions is posted throughout the document, and collated in Attachment A. Your answers to these questions and any other feedback on issues to be reviewed in the CRIS are appreciated. All submissions will be published in full on the NICNAS web site, noting that any confidential information provided will not be published. A written response to all comments will also be published on the NICNAS web site and emailed to submitters and stakeholders who register their interest.

Please submit your feedback to:

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Mail: CRIS
NICNAS
GPO Box 58
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Fax: 02 8577 8888

The contact for this project is Dr Kate Liddell on 02 8577 8894 or email: CRIS@nicnas.gov.au

Introduction

NICNAS is conducting a review of its cost recovery arrangements in accordance with the government's cost recovery policy and guidelines.

It is government policy that all NICNAS activities are cost recovered. Industry cost recovery occurs through two funding streams:

- New chemicals fees and charges – fee for service for new chemical assessments; and
- NICNAS registration – three-tiered annual fee and charge on all introducers of industrial chemicals (importers and manufacturers).

With an annual budget of approximately \$9 million, NICNAS cost recovery arrangements are considered “significant” under the government's cost recovery policy. The policy requires that cost recovery arrangements must be reviewed periodically and no less frequently than every 5 years. A review of NICNAS's cost recovery arrangements was last undertaken in 2004-05 when NICNAS was part of the TGA Group of Regulators.

In addition to the periodic review, specific consideration will be given to cost a new program of work agreed by COAG: the accelerated assessment of existing industrial chemicals (Recommendation 4.6 of the PC Report into Chemicals and Plastics Regulation, July 2008). This recommendation addresses an area identified by the PC as undermining the effectiveness of a national chemical assessment regime.

A major focus of the 2009-10 CRIS is to review the scope of NICNAS activities that have changed significantly since the last CRIS produced in 2004-05. For example, additional stakeholder outreach, greater breadth of reform programs, extra new chemical assessment products, enhanced international engagement, and additional compliance activities. It is important to review the change in scope of these activities to ensure NICNAS resources are allocated in an efficient and effective manner and the appropriate costs are recovered by suitable means.

Background

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 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 (DoFD) and outlined in the Australian Government Cost Recovery Guidelines (Cost Recovery Guidelines). The key features of this policy are set out in Attachment B. A full copy of the Cost Recovery Guidelines is available online at http://www.finance.gov.au/publications/finance-circulars/2005/09.html#FMG_4.

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.

In accordance with the Cost Recovery Guidelines the NICNAS cost recovery arrangements are scheduled to be reviewed in 2009-10. The last cost recovery review for NICNAS was undertaken in 2004-05 when NICNAS was part of the TGA group of regulators. A copy of the NICNAS CRIS 04-05 executive summary is at Attachment C.

In addition to the periodic review, specific consideration will be given to cost a new program of work agreed by COAG: the accelerated assessment of existing industrial chemicals (Recommendation 4.6 of the PC Report into Chemicals and Plastics Regulation).

A copy of the terms of reference is included at Attachment D.

A concurrent cost recovery review: revised arrangements for the scheduling of chemicals and medicines

A revised legislative framework for the scheduling of chemicals and medicines will be implemented on 1 July 2010. The Department of Health and Ageing and the Therapeutic Goods Administration (TGA) is concurrently considering the cost recovery arrangements for scheduling of chemicals and medicines. A draft CRIS was released for public consultation between January and March 2010.

Cost recovery arrangements are currently being further examined by the TGA and the Department of Health and Ageing in light of comments received on the draft CRIS. More details on the draft CRIS are available on this website, <http://www.tga.gov.au/ndpsc/scheduling-revised.htm>.

Substances covered by scheduling arrangements may also be regulated through Commonwealth legislation administered by NICNAS.

What is cost recovery?

(Extract from the Australian Government Cost Recovery Guidelines, July 2005, ISBN 0-9757365-5-8)

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 extraction of money by a public authority for public purpose, enforceable by law, and which is not a payment for services rendered.

Why have cost recovery?

(Extract from the Australian Government Cost Recovery Guidelines, July 2005, ISBN 0-9757365-5-8)

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.

However, cost recovery may not be warranted where:

- it is not cost effective; or
- it would be inconsistent with government policy objectives; or
- it would unduly stifle competition and industry innovation (for example through ‘free rider’ effects).

History of NICNAS Cost Recovery

The NICNAS Director administers the *Industrial Chemicals (Notification and Assessment) Act 1989* (IC(NA) Act). The Director manages the day to day administration of the Act under the direction of the Secretary of the Department of Health and Ageing.

Cost recovery arrangements for activities undertaken by NICNAS to regulate industrial chemicals were introduced with the IC(NA) Act in 1989. Fees and charges were initially established to recover 50% of NICNAS’s costs. The majority of costs were recovered via application fees for new chemical and priority existing chemical assessment services. This was reviewed in 1997 when the then Minister for Workplace Relations and Small Business approved changes to move NICNAS to 97% cost recovery of regulatory activities from industry. The changes included:

- a) full cost recovery for the assessment of new chemicals through a system of fees for service;

- b) full cost recovery for existing chemical assessments via registration fees and charges;
- c) full cost recovery of NICNAS scheme support via registration fees and charges;
- d) 50% cost recovery of compliance activities via registration fees and charges;
- e) government funding for services provided to government that are considered to be outside the regulatory scheme; and
- f) government funding of appeals against NICNAS decisions.

The initial NICNAS registration charge, as introduced in 1998, was a two-tier system payable where the value of the chemicals introduced in the registration year exceeded \$500,000 but was less than \$5,000,000 (equivalent to the current tier 2 registration category), and where the value of the chemicals introduced in the registration year exceeded \$5,000,000 (equivalent to the current tier 3 registration category). This two-tier system continued unchanged until the IC(NA) Act was amended in 2004 with the introduction of a registration fee where the value of the chemicals introduced in the registration year was \$500,000 or less (no lower threshold).

In 2004, in conjunction with the introduction of a registration fee for tier 1 introducers, government funding was ceased for:

- \$120,000 to support part of the compliance program to inform and monitor small to medium enterprise compliance with the Scheme; and
- \$325,000 to cover the cost of services to government that relate to the regulation of industrial chemicals

This was a change to the NICNAS cost recovery policy that had previously excluded these costs.

NICNAS fees and charges are determined annually in consultation with the NICNAS Industry Government Governance Committee (IGCC). The IGCC was established in 1997 by the then Minister for Workplace Relations and Small Business to ensure that industry has the opportunity to participate in the NICNAS budgetary process. The IGCC provides the opportunity for industry and government input into the NICNAS planning process and provides a forum for discussion on NICNAS performance.

Under the Terms of Reference, the IGCC is charged with:

- a) reviewing the utilisation of resources against NICNAS objectives;
- b) reviewing the performance of NICNAS against agreed performance indicators (including those established in the NICNAS Service Charter and Corporate Plan), and in particular the impact on industry and the protection of human health and the environment;
- c) developing strategies for improving the efficiency and effectiveness of NICNAS operations within the context of (i) established goals and objectives and (ii) developing and emerging issues; and
- d) developing compliance strategies and monitoring the effectiveness of these strategies in promoting compliance with the Scheme.

The table below provides a summary of fee increases for new chemical assessments and NICNAS registration since the last CRIS in 2004-05. NICNAS fees and charges are indexed by a model agreed by IGCC in 2004-05. The index model used is comprised of 75% of the Wage Price Index (WPI), reflecting average wage movements, and 25% 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 IGCC together with any additional regulatory cost pressures. The last time NICNAS increased the registration fees and charges was for the 2007-08 registration year.

Table 1: Summary for fee increases for new chemical assessments and NICNAS registration since 2004-05.

Financial year	Percentage increase from preceding year	Increase applicable to new chemicals fees and charges	Increase applicable to registration fees and charges
2004-05	5.1% (agreed increase above CIP/WPI)	Yes	No
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

Part A - Periodic Review

Introduction and methodology

There are a number of objectives for the periodic review as detailed in the terms of reference (Attachment D). These include, but are not limited to:

- ensuring compliance with the Government's policy and guidelines for cost recovery for activities undertaken by NICNAS;
- identifying all costs and ensure an appropriate mechanism to recover these costs is established; and
- developing a cost recovery policy reference document.

A major focus of the 2009-10 CRIS is to review the scope of NICNAS activities that have changed significantly since the last CRIS produced in 2004-05. For example, additional stakeholder outreach, greater breadth and complexity of reform programs, extra new chemical assessment products, enhanced international engagement, and additional compliance activities. It is important to review the change in scope of these activities to ensure NICNAS resources are allocated in an efficient and effective manner and the costs are recovered appropriately.

NICNAS registration fees and charges

At present most NICNAS activities (except new chemicals assessments) are funded from NICNAS registration funds. The NICNAS registration is composed of a fee for the administrative aspects and a charge, as shown in table 2 below. The administration fee is payable by all introducers of relevant industrial chemicals. The charge is imposed on those companies introducing industrial chemicals with a value over \$500,000 per registration year (tiers 2 and 3). To ensure compliance with the government's policy and guidelines for cost recovery it is essential to ensure NICNAS has applied the registration administration fee and registration charges in an equitable manner.

Table 2: NICNAS registration fees and charges for the NICNAS registration year 2008-09 and 2009-10.

Tier	Applicable introduction value*	Administration Fee	Charge	Total payable
1	\$1 - \$499,999	\$381	\$0	\$381
2	\$500,000 - \$4,999,999	\$381	\$1,141	\$1522
3	\$5,000,000 or more	\$381	\$8500	\$8,881

** The three levels of registration are based on the total value of industrial chemicals imported and /or manufactured each year. The registration year runs from 1 September to 31 August in the following year.*

In our preliminary analysis, a number of areas have been identified where the registration fee and charge may not be equitable. In particular, the proportion of the registration fees and charges payable by each tier is unequal when compared to the introduction value (see table 3). These issues are explored below.

Table 3: Summary of amount payable and proportion of introduction value

Introduction value	Amount payable 2009-10	Percentage of introduction value		Introduction value	Amount payable 2009-10	Percentage of introduction value
\$1,000	\$381	38.1		\$3,000,000	\$1,522	0.05
\$10,000	\$381	3.81		\$4,000,000	\$1,522	0.04
\$100,000	\$381	0.38		\$5,000,000	\$8,881	0.18
\$500,000	\$1,522	0.30		\$10,000,000	\$8,881	0.09
\$1,000,000	\$1,522	0.15		\$50,000,000	\$8,881	0.02
\$2,000,000	\$1,522	0.08		\$100,000,000	\$8,881	0.01

Micro-businesses

Many micro-businesses introduce industrial chemicals into Australia at values less than the lowest level (tier 1) NICNAS registration administration fee (\$381 for the 2009-10 registration year).

As detailed in the history of NICNAS cost recovery, prior to 2004-05 NICNAS registration applied only to those companies introducing relevant industrial chemicals with a value over \$500,000 and a two-tier registration structure was in operation. In 2004-05 NICNAS introduced a third registration tier (tier 1) to include introducers of industrial chemicals whose introduction of industrial chemicals is less than \$500,000 per registration year with no lower threshold. This change was implemented in response to recommendation 10.1 from the NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative, June 2003 that stated:

“NICNAS introduces mandatory company registrations of all chemical introducers currently below the current \$500,000 threshold. An administrative fee only should apply.”

In the *Final Report and Recommendation for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative, June 2003*, the LRCC Task Force recognised that an effective compliance program must underpin all NICNAS’s activities in order to maintain industry and public confidence in NICNAS and the LRCC reforms. In its report the LRCC Task Force also noted that mandatory registration can increase the compliance burden of those small businesses, but their view was that the benefits will outweigh the costs in the longer term and noted that the only financial cost is likely to be a small annual administrative fee.

Since this policy change there have been a number of representations made from micro businesses and hobbyists, stating that the tier 1 NICNAS registration fee is an unreasonable burden.

Preliminary analysis of the data on the value of chemicals introduced in the 2008-09 registration year (see table 4 below) indicates that there were approximately 94 companies introducing a total value of industrial chemicals less than \$381 (the tier 1 registration administration fee).

Table 4: Analysis of NICNAS registration fees and charges versus industrial chemical introduction value for the NICNAS registration year 2008-09.

Tier	Applicable introduction value ¹	Registration fee and charge ²	Number of companies ³	Total value of chemicals introduced	Number of companies
1	\$1 - \$499,999	\$381	3112	< \$381	94
				\$381 - \$499	23
				\$500 - \$999	81
				\$1,000 - \$9,999	696
				\$10,000 - \$499,999	2218
2	\$500,000 - \$4,999,999	\$1,522	751	<\$1.5 m	421
				>\$1.5 m	330
3	\$5,000,000 or more	\$8,881	308	< \$10 m	113
				\$10 m - \$49 m	138
				\$50 m - \$100 m	32
				> \$100 m	25

Amount payable as percentage of minimum introduction value

When first introduced in 1998, the registration charge payable where the value of the chemicals introduced in the registration year exceeded \$500,000 but was less than \$5,000,000 (equivalent to the current tier 2 registration category) was \$1,200. This registration charge equalled 0.24% of the minimum introduction value (\$500,000). Similarly, the registration charge payable where the value of the chemicals introduced in the registration year exceeded \$5,000,000 (equivalent to the current tier 3 registration category) was initially set at \$7,000. This charge equalled 0.14% of the minimum introduction value.

In 2009-10, the amount payable by tier 2 registrants is \$1,522 (equivalent to 0.3% of the minimum introduction value) and \$8,881 for tier 3 registrants (equivalent to 0.18% of the minimum introduction value).

¹ The three levels of registration are based on the total value of industrial chemicals imported and /or manufactured each year. The registration year runs from 1 September to 31 August in the following year.

² Same registration fee and charge applied in 2008-09 and 2009-10.

³ Only includes those companies where chemicals were actually introduced and the value is known.

Table 5 below summarises the amount payable by registrants in tier 2 and 3 as a percentage of the minimum introduction value (based on the 2009-10 fees and charges). It is clear that the amount payable per tier does not represent the same proportion of the minimum introduction threshold across the two tiers.

Table 5: Summary of amount payable and proportion of introduction value by tier

Tier	Minimum introduction value	Amount payable 2009-10	Percentage of minimum introduction value
1	\$500,000	\$1,522	0.30
2	\$5,000,000	\$8,881	0.18

Introduction of an additional tier (tier 4)

A number of large companies introduce industrial chemicals into Australia at values greater than \$50 million (see table 4). The company registration scheme has been reviewed previously and the introduction of additional tiers has been recommended for companies with high value introductions. To date these recommendations have not been implemented.

Impact of inflation on introduction thresholds

The minimum introduction value thresholds for tiers 2 and 3 have not changed since the registration charge was introduced in 1998. In comparison, over the same period of time the CPI has increased by approximately 30%. This may have resulted in a situation where inflation has pushed introducers into a higher registration tier without a real increase in the value of the chemicals they are introducing.

If the tier 2 and tier 3 minimum introduction values are increased by 30% the minimum introduction value thresholds would increase to be:

- Tier 2 - \$650,000 (\$500,000 x 130%)
- Tier 3 - \$6,500,000 (\$5,000,000 x 130%)

Questions

1. What services do tier 1 registrants require from NICNAS?
2. Are there other fee structures which would provide a more equitable distribution of the funding burden?
3. 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 IC(NA) Act?

Late Penalty Fees

A 15% penalty fee applies to all registration charges and renewal fees that remain outstanding after the due date. This was introduced in 2003-04 to improve scheme equity and better target NICNAS compliance effort.

Analyses of NICNAS records show that significant NICNAS resources are expended to follow up late payments. The recovery of late penalty fees is administratively burdensome.

As shown in table 6 below, the number of late registrations received from tier 1 introducers was 10% of the total tier 1 registrations for the 2008-09 registration year. Likewise, approximately 10% of tier 2 registrants paid late and 5% of tier 3 registrants.

Table 6: Number of late payments received for the 2008/09 NICNAS registration year

Tier	No. of late registrations received	No. late as % of total registrations per tier	Late penalty fee
1	363	10%	\$57
2	79	10%	\$228
3	18	5%	\$1,332

Questions:

4. Is the application of a late penalty fee a deterrent to late payment of fees?
5. What other mechanisms could be used to encourage registration payments to be made on time?

Multi-year registration cycle

The NICNAS registration cycle extends from 1 September to 30 August. NICNAS expends a lot of resources managing the renewal of approximately 4,500 registrants each year.

The introduction of an optional multiple-year registration cycle instead of the current annual registration cycle would reduce the administrative burden on NICNAS, which could be passed on as a reduced administration fee. Similarly, it would be expected that there would be a lower administrative burden on registrants.

Questions:

6. 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?

Align the NICNAS registration cycle with the financial year

As the current NICNAS registration cycle extends from 1 September to 30 August, NICNAS can complete end of year financial reporting obligations prior to undertaking work related to registration renewal. The alignment of the registration year with the financial year, however, may be beneficial to registrants and would allow NICNAS to more accurately predict the expected revenue from registration earlier in the financial year.

Questions:

7. Would the alignment of the NICNAS registration cycle with the financial year be beneficial? Please supply supporting information.

New chemicals fees and charges

New chemicals are funded on a fee for service basis from new chemicals fees and charges. A number of new assessment categories and associated fees for new chemicals have been introduced since the last CRIS. An aim of the review is to validate the fees for each assessment category to ensure it matches the cost (through activity costing) and that these charges are compliant with the government's cost recovery policy and guidelines.

Preliminary analysis of the new chemicals fees and charges has highlighted some areas for further investigation. These are discussed below.

Cross subsidisation of new chemical activities from registration funds

The 2004-05 cost recovery review noted that there was some cross subsidisation between new chemical assessments and registration income in an effort to limit the introduction cost of new innovative chemicals coming onto the market. Stakeholder comments at the time indicated that the level of cross subsidisation was acceptable. Cross subsidisation is not supported in the government's cost recovery guidelines.

Questions:

8. 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?
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Screening fee

In 2007 NICNAS introduced an enhanced screening framework. Under the framework NICNAS assesses the quality of the application and specifies the timeframe within which the applicant must address any data gaps. Following administrative and technical screening, the application is determined to be either complete (and the assessment clock can start), incomplete (outstanding data that can be easily rectified and the assessment clock can start), or substantially deficient. The timeframe specified for addressing outstanding matters is 14 days for permit applications and 28 days for certificate applications. The notifier also has the option of submitting a timetable for addressing the outstanding matters.

The new screening framework has allowed NICNAS to return both grossly deficient submissions and submissions where the notifier does not respond to NICNAS's requests to address outstanding matters. This has resulted in NICNAS no longer holding applications for an indefinite period of time while waiting for additional data, and has allowed better management of resources and minimised flow through time for applications.

Under the enhanced screening framework, NICNAS introduced a screening fee/ refund policy. This policy was published in the February 2007 Chemical Gazette⁴. The refund given under this policy is:

- 100% (minus the cost for an AICS search) where the chemical is found to be an existing chemical during the administrative screening stage;
- 90% where the application is withdrawn after administrative screening;

⁴ http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2007feb_whole.pdf

- 70-85% (dependent on assessment type) where the application is withdrawn after administrative and technical screening;
- a percentage based on the stage of assessment where the application is withdrawn after the assessment has started (e.g. 65% for a STD withdrawn at day 45); and
- 0% where the application is withdrawn after the assessment is complete.

This refund policy is administratively burdensome for NICNAS. A simpler policy might be to introduce a standard non-refundable screening fee. This standard non-refundable screening fee would not be returned if the application was withdrawn at any stage during the screening process. The current policy for refunds where an application is withdrawn during the assessment process would remain.

It should be noted that recommendation 4.5 of the PC report stated: *The Australian Government should introduce a statutory timeframe for the technical screening of applications by NICNAS.* This issue is outside the scope of this review.

Questions:

9. 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?

Electronic template rebate

It is current practice to rebate up to 15% of the new chemicals notification application fee when submissions are made using an agreed electronic template. This rebate was introduced as an incentive for applicants to submit data in the format of the assessment report, thus standardising the format, quality and consistency of data provided in notification statements by applicants on toxicity, exposure and chemistry; assisting the applicant in meeting their notification obligations under the IC(NA) Act; and assisting NICNAS in the preparation of the assessment reports. NICNAS has noted that the level of use of electronic templates has been high.

The process of calculating the percentage rebate requires NICNAS and DEWHA, where appropriate, to review the application quality against set criteria. This process adds additional time to the assessment. Recent experience suggests that the typical rebate given for using the electronic template is approximately 5% due to incomplete submissions or applications not of sufficient quality for direct use by NICNAS. Therefore considerable NICNAS resources are expended in processing refunds for relatively small amounts of money.

Questions:

10. 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?

Secondary notification preliminary review

As part of the post assessment obligations industry must advise NICNAS of any change in circumstances to those advised in the original notification, e.g. change in volume, use, new adverse health and/or environmental effects. NICNAS then makes a decision on whether the changed circumstances impact on the risk posed by its use and whether a revised risk assessment of the

chemical is warranted. In making a decision NICNAS discusses the change of circumstances with the applicant and reviews the data. At present this work is not charged as a direct fee for service.

Questions:

11. 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?

Other Issues

Reform activities

NICNAS reform activities have been primarily financed from reserves of undrawn appropriations. The quantum of reform work is determined annually and in consultation with the NICNAS IGCC. This approach, while long standing, has resulted in NICNAS proposing and/or running a deficit budget over the past several years. This annual consideration of reform activities does not provide certainty for organisational planning and resource allocation nor for industry and other stakeholders in the delivery of reform outcomes.

The number and complexity of regulatory reform activities has increased significantly over recent years. NICNAS is currently undertaking reform activities for hard surface disinfectants, nanotechnology regulation, evaluation of low regulatory concern chemicals, finalisation of the reforms at the cosmetic therapeutic interface and reforms relating to the national inventory of chemical substances.

As part of this review, NICNAS will investigate options to incorporate reform activities into mainstream funding arrangements. This will facilitate more predictable resource allocation for reform activities. As part of its annual business planning cycle NICNAS will consider the quantum of reform activities that can be undertaken within budgetary constraints.

Questions:

12. What factors should be considered in determining the level of reform activity NICNAS undertakes?
13. What are the implications of NICNAS charging a special levy or a fee to a particular industry sector where the reform activities are specific to that sector only? E.g., cosmetics and disinfectants.
14. How could this levy be structured alongside a multi-year funding cycle?

Office of Best Practice Regulation Requirements

In 2006, changes were made to the government's best practice regulation requirements which mandate a regulatory impact analysis of all regulatory and quasi-regulatory decisions. This has meant that all changes to NICNAS regulations and legislation, including those associated with reforms, require a regulatory impact analysis.

Any regulatory activity necessitates an assessment of the impact on business and individuals or the economy. A regulatory impact analysis must take into account compliance costs and competitive disadvantage to industry.

The resources and costs involved in undertaking a regulatory impact analysis have not been included in the current NICNAS fee structure.

Questions:

15. 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?

NICNAS 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:

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

During the last few years NICNAS has seen a 3% drop in registration revenue and a 40% drop in new chemical assessment revenue.

A reserve is used as a risk mitigation strategy by cost recovered agencies to allow the business of the agency to continue business in the event that there is a shortfall in income and to prevent the need to use the budget process to make up the deficit. NICNAS currently holds a 10% contingency fund (equivalent to just over one month's operating expenses) in reserves agreed to by the IGCC. It has been noted, however, that other comparable agencies often hold a reserve equal to 3 months operating expenses which would be approximately 25% of the NICNAS annual revenue.

Questions:

16. What is an adequate level of reserves for NICNAS to enable the organisation to continue its business?
17. What strategies could be used to improve the predictability of NICNAS annual income?

Investment in training and new assessment methodologies

The introduction of new technologies, such as nanotechnology, and changes in international risk assessment methodologies and best practice techniques means that training of NICNAS staff is paramount in maintaining high quality regulatory science. An aim of the CRIS will be to investigate an appropriate investment in training and software needed to ensure that NICNAS assessments meet contemporary scientific assessment standards.

Quantitative Structure-Activity Relationship modelling (QSAR) is an essential tool for the prioritisation and assessment of chemicals for which there is very little experimental data. In order to use this technique, NICNAS must purchase and maintain the necessary software and train technical staff in its use.

NICNAS has recently developed a strategy for the regulation of industrial nanomaterials that equips the agency to understand and appropriately assess the novel properties presented by these substances. This requires developing risk assessment capability, determining data requirements and

benchmarking NICNAS risk assessment methodology and practices to meet international best practice. Training of technical staff and maintaining international and national linkages with comparable regulatory agencies is required to ensure NICNAS can adequately assess these substances.

Questions:

18. What factors should be considered when determining the appropriate level of investment in training and new assessment technologies?

Resources for maintaining integrity of the Scheme

While the assessment function is seen as a core NICNAS activity, NICNAS resources are expended on functions such as compliance and stakeholder outreach. These activities are integral to the integrity of the Scheme and it is therefore imperative that NICNAS allocates adequate resources to these tasks.

Significant changes to the overall Scheme were the result of the 2004-05 Low Regulatory Concern Chemicals reforms. These reforms introduced:

- mandatory NICNAS registration of all introducers of industrial chemicals;
- expansion of the scope of new chemicals that are exempt from notification and assessment balanced by an annual reporting and record keeping requirement; and
- self-assessments for low risk new chemicals.

These changes reduced the premarket assessment effort for industry and NICNAS on chemicals of low regulatory concern enabling the fast tracking of these chemicals onto the market. To maintain public and industry confidence with respect to the maintenance of health and environmental standards and the integrity of the Scheme, the reduction of premarket assessment effort is balanced by post-market compliance activities.

The introduction of mandatory NICNAS registration for all introducers of industrial chemicals has increased the number of registrants from approximately 900 to almost 5000. This change has substantially increased the effort associated with managing the registration renewal process.

Since the last CRIS in 2004-05, NICNAS has increased the number of stakeholder outreach activities undertaken. These include providing guidance through information sessions, training workshops, and presentations at conferences. NICNAS has also increased the publication frequency of NICNAS matters from 2-3 to 5-6 times per year and has added the CEF Bulletin which is published 2-3 times per year.

Questions:

19. What factors should influence the amount of compliance effort spent on a particular activity?
20. What factors should be considered when determining the level and type of outreach activities undertaken?

ANAO Recommendation

The ANAO made the following recommendation in the ANAO Audit Report #23 2007-08, *The Management of Cost Recovery by Selected Regulators*:

The ANAO recommends that, in order to increase transparency for stakeholders and assist staff to apply to Government's cost recovery guidelines, agencies should:

- *overtime, consolidate their cost recovery policy and procedures into a single reference document; and*
- *ensure documentation outlining their costing systems is up-to-date, accessible and easily understood.*

NICNAS will implement this recommendation as part of the cost recovery review.

Questions:

21. Are there any specific items you would like to see included in a document outlining NICNAS's cost recovery policy and procedures?

Definition of Chargeable Person

The IC(NA) Act defines a chargeable person as a person who proposes to introduce relevant industrial chemicals⁵. The IC(NA) Act defines introduction as the importation or manufacture in Australia of the chemical. This means that the NICNAS registration fees and charges are applicable to all importers or Australian manufactures of relevant industrial chemicals, but not applicable to all users along the supply chain (downstream users). For example, organisations that purchase relevant industrial chemicals as raw materials within Australia and blend them into a product (without a chemical reaction occurring) are not required to be registered with NICNAS.

Questions:

22. Is there a reason to expand the definition of a chargeable person to include down stream users of industrial chemicals? What factors should be considered in coming to this view?

Annual indexation of 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% of the WPI, reflecting average wage movements, and 25% of the 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.

One of NICNAS's largest costs is staff salaries and entitlements such as leave and superannuation. In recent years that the increase in salaries to staff under the Department of Health and Ageing

⁵ Relevant industrial chemicals are chemicals that have an industrial use not including: use as an agricultural or veterinary chemical or constituent of an agricultural or veterinary chemical, therapeutic use or use as an ingredient or component in the preparation or manufacture of goods for therapeutic use, use as food intended for consumption by humans or animals or as constituent of such food, or use as a food additive; and is not a naturally-occurring chemical, biological material, an incidentally-produced chemical, or a reaction intermediate.

Certified Agreement is usually greater than the index applied to the fees and charges. This has meant that NICNAS has reduced activity or had a deficit budget.

It has been noted that other comparable agencies use a different ratio of the WPI and CPI figures, e.g., 50:50 or 100% CPI. Indexing the fees and charges by the CPI alone, however, would not recover all of the staff costs when the WPI is greater than the CPI.

The advantages of automatic indexation are stability and surety for NICNAS and industry. NICNAS would be able to better predict available resource levels and therefore plan projects that run over multiple years.

Questions:

23. What factors should influence the indexation model for adjusting fees and charges?

24. What are the implications of introducing an automatic annual adjustment?

Identification of fee for service activities

Within the overall Australian regulatory framework for industrial chemicals NICNAS has a specific role as the hazard and risk assessment agency. As part of this function NICNAS makes recommendations to standard setting bodies and industry for risk management measures as determined by scientific assessment. In its study on chemicals and plastics regulation (PC Report), the Productivity Commission recommended a new governance structure for chemicals and plastics regulation where the assessment of hazards and risks of chemicals is a natural science based function undertaken under statutory independence. Accordingly the PC recommended that NICNAS's functions be limited to scientific assessment of hazards and risks of industrial chemicals. This governance structure has been agreed by COAG.

The government's cost recovery guidelines state:

“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 cost of individual activities, levies do not have the efficiency advantages of fees. They may also place less direct pressure on the agency to improve efficiency. Therefore, it is desirable, where possible to charge for activities directly through fees.”

Thus, as part of the CRIS NICNAS will investigate if there are any other activities not currently charged as a fee for service where it would be appropriate to do so. Suggested activities include training on notification processes and implemented reforms where the person receiving the training is a direct beneficiary, technical services relevant to industrial chemicals, and authorisations for the export and import of chemicals listed under the Rotterdam Convention.

Questions:

25. What do you believe is the most equitable manner in which to cost recover these activities? Should it be through a fee for service or a levy?

Other unidentified issues

A number of issues with NICNAS fees and charges have been identified and discussed above. There may be other issues, however, that you would like to see addressed in the CRIS.

Questions:

26. Are there any other issues with the NICNAS fees and charges you would like to see addressed in the CRIS?

Part B - Accelerated Assessment of Existing Industrial Chemicals

Background

The Australian Inventory of Chemical Substances (AICS) was established for the purposes of implementing the *Industrial Chemicals (Notification and Assessment) Act 1989*. It includes those chemical substances that were reported by industry to be in use in Australia between 1977–1990, 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.

The initial AICS contained industrial chemicals in commercial use in Australia as at 28 February 1990. Of the approximately 39,000 chemicals currently on AICS, approximately 38,000 were “grandfathered” as existing chemicals 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 150 of 38,000) have been subsequently assessed by NICNAS, including as priority existing chemicals (PECs), under the current Existing Chemicals Program.

Review of NICNAS Existing Chemicals Program

In 2006, NICNAS undertook a review of its Existing Chemicals Program. This review found that the Existing Chemical Program was very complex and its lack of flexibility meant that it was unable to respond in a timely and resource efficient manner to the variety of stakeholder concerns. Following extensive consultation with community, industry and government recommendations were made to improve the flexibility and transparency of the existing chemicals program. Several recommendations related to the screening of all AICS-listed chemicals in use to prioritise chemicals for further assessment. The review acknowledged that an increased knowledge about the hazards and risks of existing chemicals in use in Australia would benefit community, industry and government as realistic and practical controls could then be applied to minimise the risks to human health and the environment. The review also acknowledged that the reforms were consistent with international best practice regulation for existing industrial chemicals. The outcome of this review was agreed by government and NICNAS has been progressing the implementation of these recommendations since this time.

Productivity Commission Review

In 2007-08, the Productivity Commission (PC) undertook a study to investigate the current system of regulation of chemicals and plastics in Australia. The resulting report, *Chemicals and Plastics Regulation, Research Report, 2008* (PC report) (available at <http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport>), assessed the effectiveness of chemicals and plastics regulations in addressing human health and safety and environmental issues. The PC report proposed a governance framework that enhances national uniformity and highlighted 29 specific recommendations ranging from significant governance changes to specific reforms within each of the regulatory streams. Eight of the recommendations have direct implications for NICNAS, with recommendation 4.6 stating that NICNAS should implement a program to greatly accelerate the assessment of existing chemicals.

Addressing the Regulatory Gap

Recommendation 4.6 of the PC report addresses an area identified by the PC as undermining the effectiveness of a national chemical assessment regime. This recommendation builds on the outcomes of the 2006 Review of the NICNAS Existing Chemicals Program.

The PC recommended that *NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that:*

- *screens all existing chemicals to develop a list of high-priority chemicals for assessment;*
- *makes greater use of simulation techniques based on the hazards of chemical analogues;*
- *review the scope for recognising the existing chemical assessment schemes of a range of other countries as ‘approved foreign schemes’. Priorities should be the schemes operated by Canada, the European Union and the United States; and*
- *the Australian Government should meet the costs of screening all existing chemicals from budget funding, NICNAS should continue to recover the costs of subsequent assessment of chemicals of concern.*

In November 2009, 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.”

The first stage of the accelerated program will be a prioritisation process whereby the known hazards and potential exposures of the chemicals on the Australian inventory will be evaluated in an efficient manner, building on approaches and screening tools from a similar exercise undertaken by Canada, in order to develop a list of priority chemicals for assessment. The envisaged prioritisation process would systematically and efficiently examine all industrial chemicals thereby accelerating the development of a list of existing chemicals of concern.

The outcomes of the prioritisation will redress the current regulatory gap by focusing scientific analysis on potential higher risk chemicals, if considered necessary, with appropriate risk management recommendations made to national standard setting bodies and responsible agencies (e.g., the National Drugs and Poison Schedule Committee⁶, Safe Work Australia), State and Territory agencies, and industry. Such controls may include labelling for consumer information, exposure standards for workers and transport controls. The consequence of not accelerating the assessment of existing chemicals is that there will continue to be a regulatory gap, where chemicals in commerce have not been assessed for health and environmental impacts and adequate controls may not be in place.

Several overseas countries have implemented programs for screening and assessing existing chemicals. Canada undertook a prioritisation activity on their national inventory of 23,000 chemicals over a period of seven years (1999 to 2006) using screening tools specifically developed for prioritisation. The European Union (EU) under the Registration, Evaluation, Authorisation and

⁶ A revised legislative framework for the scheduling of chemicals and medicines, including new decision making powers, will be implemented on 1 July 2010. Revised administrative arrangements include changes to the structure of the scheduling committee and a new streamlined decision making process. Detailed information concerning the revised scheduling arrangements can be found at <http://www.tga.gov.au/ndpsc/scheduling-revised.htm>.

Restriction of Chemicals (REACH) legislation requires manufacturers and importers to re-register chemicals placed in the EU market. Under REACH the burden of proof to support the use of chemicals is placed on industry. This includes the provision of chemical safety data and exposure information, including manufactured/imported volumes and use information on each chemical, and the preparation of Chemical Safety Reports where necessary. The United States is working with industry to assess high and moderate production volume chemicals and the Congress is in the process of modernising and strengthening the effectiveness of the Toxic Substances Control Act to ensure that chemicals in commerce are safe.

If prioritisation of the inventory takes a long period of time, Australia will fall behind other comparable overseas regulatory authorities in Canada, USA and Europe. Completing this project within a reasonable period of time creates opportunities for work sharing by regulatory agencies and simultaneous industry submission of information in multiple countries, thus reducing Australia's assessment effort and the regulatory burden on industry.

There are many benefits of addressing this regulatory gap through the prioritisation project. Some of these are:

- Identification of chemicals in use in Australia.
- Increased knowledge about the hazards and risks of existing chemicals in use in Australia for better decision-making by the public, industry and government to reduce the harmful effects of these chemicals.
- Provide greater public confidence in the Australian chemical industry and in the regulation of industrial chemicals.
- Prevents Australia falling behind in chemical management in comparison to comparable overseas countries such as Canada, USA and Europe.
- Creates greater opportunities for international cooperation on chemical management.
- Assists industry in choosing safer chemicals by providing greater hazard/risk information on industrial chemicals.
- Increased capability to respond to major adverse events with the provision of hazard/risk information to relevant domestic authorities.
- Allow NICNAS to effectively and efficiently respond to public and industry enquiries on health and environmental effects of chemicals.
- Builds NICNAS capabilities in the use and application of predictive models and techniques.

This proposal addresses one reform in a whole-of-government chemical regulatory reform agenda and long-standing community concern about the lack of knowledge about chemicals currently in use and their potential adverse human health and environmental effects.

Cost Recovery Arrangements

The strategy for chemicals and plastics regulatory reforms informed by the PC report was considered by the Council of Australian Governments (COAG) at its meeting on 29 November 2008. COAG supported the package of reforms proposed by the PC.

The Productivity Commission recommended that the Australian Government should meet the cost of the proposed screening of existing chemicals from budget funding and that NICNAS should recover subsequent assessment costs from industry. COAG, however, noted that budget funding of this proposal is not consistent with the current cost recovery policy for NICNAS. The government has now decided to move forward with implementing this recommendation using a cost recovery model.

Questions:

27. 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?
28. What is the most equitable manner to raise funds to support prioritisation of chemicals on the inventory?

Questions

1. What services do tier 1 registrants require from NICNAS?
2. Are there other fee structures which would provide a more equitable distribution of the funding burden?
3. 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 IC(NA) Act?
4. Is the application of a late penalty fee a deterrent to late payment of fees?
5. What other mechanisms could be used to encourage registration payments to be made on time?
6. 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?
7. Would the alignment of the NICNAS registration cycle with the financial year be beneficial? Please supply supporting information.
8. 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?
9. 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?
10. 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?
11. 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?
12. What factors should be considered in determining the level of reform activity NICNAS undertakes?
13. What are the implications of NICNAS charging a special levy or a fee to a particular industry sector where the reform activities are specific to that sector only? E.g., cosmetics and disinfectants.
14. How could this levy be structured alongside a multi-year funding cycle?
15. 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?
16. What is an adequate level of reserves for NICNAS to enable the organisation to continue its business?
 17. What strategies could be used to improve the predictability of NICNAS annual income?
 18. What factors should be considered when determining the appropriate level of investment in training and new assessment technologies?
 19. What factors should influence the amount of compliance effort spent on a particular activity?
 20. What factors should be considered when determining the level and type of outreach activities undertaken?
 21. Are there any specific items you would like to see included in a document outlining NICNAS's cost recovery policy and procedures?
 22. Is there a reason to expand the definition of a chargeable person to include down stream users of industrial chemicals? What factors should be considered in coming to this view?
 23. What factors should influence the indexation model for adjusting fees and charges?
 24. What are the implications of introducing an automatic annual adjustment?
 25. What do you believe is the most equitable manner in which to cost recover these activities? Should it be through a fee for service or a levy?
 26. Are there any other issues with the NICNAS fees and charges you would like to see addressed in the CRIS?
 27. 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?
 28. What is the most equitable manner to raise funds to support prioritisation of chemicals on the inventory?

Key points regarding the application of the Cost Recovery policy

(Extract from Finance Circular No. 2005/09, Department of Finance and Administration).

1. Agencies should set charges to recover all the costs of products or services where it is efficient to do so, with partial CR to apply only where new arrangements are phased in, where there are government endorsed community service obligations, or for explicit government policy purposes.
1. CR should not be applied where it is not cost effective, where it is inconsistent with government policy objectives or where it would unduly stifle competition or industry innovation.
2. Any charges should reflect the costs of providing the product or service and should generally be imposed on a fee-for-service basis or, where efficient, as a levy.
3. Agencies should ensure that all CR arrangements have clear legal authority for the imposition of charges.
4. Costs that are not directly related or integral to the provision of products or services (e.g. some policy and parliamentary servicing functions) should not be recovered. Agencies that undertake regulatory activities should generally include administration costs when determining appropriate charges.
5. Where possible CR should be undertaken on an activity (or activity group) basis rather than across the agency as a whole. CR targets on an agency-wide basis will be discontinued.
6. Products and services funded through the budget process form an agency's 'basic information product set' and should not be cost recovered. Commercial, additional and incremental products and services that are not funded through the budget process fall outside of an agency's 'basic product set' and may be appropriate to cost recover.
7. Portfolio Ministers should determine the most appropriate consultative mechanisms for their agencies' CR arrangements, where relevant.
8. CR arrangements will be considered significant ('significant CR arrangements') depending on both the amount of revenue and the impact on stakeholders. A 'significant CR arrangement' is one where:
 - an agency's total CR receipts equal \$5 million or more per annum – in this case every CR arrangement within the agency is considered, prima facie, to be significant, regardless of individual activity totals; or
 - an agency's CR receipts are below \$5 million per annum, but stakeholders are likely to be materially affected by the CR initiative; or
 - Ministers have determined the activity to be significant on a case-by-case basis.
9. All agencies with significant CR arrangements will need to prepare Cost Recovery Impact Statements (CRIS) when:
 - reviews consistent with the Australian Government's review schedule for existing cost recovery arrangements are undertaken; or
 - new cost recovery arrangements are proposed; or
 - material amendments are made to existing arrangements (a general rule-of-thumb is that price changes greater than the Consumer Price Index would be considered

material. However, in making a decision about materiality, agencies should also consider the likely impact on stakeholders); or

- periodic reviews of cost recovery arrangements are undertaken.
10. The chief executive, secretary or board must certify that the CRIS complies with the CR policy and provide a copy to the Department of Finance and Deregulation. Agencies must include a summary of the CRIS in their portfolio budget submissions and statements.
 11. A CRIS will not be required where a Regulation Impact Statement that also addresses CR arrangements against the revised Guidelines has been prepared.
 12. Agencies with significant CR arrangements should ensure that they undertake appropriate stakeholder consultation, including with relevant departments.
 13. Agencies are to review all significant CR arrangements periodically, but no less frequently than every five years.
 14. Agencies will need to separately identify all CR revenues in notes to financial statements – to be published in portfolio budget statements and annual reports consistent with the Finance Minister’s Orders.
 15. Portfolio Ministers are responsible for ensuring that the CR arrangements of agencies within their portfolios comply with the policy and will report on implementation and compliance in portfolio budget submissions.
 16. Where a Government entity considers that a significant cost recovery arrangement that is new, materially amended or which has been reviewed, should be exempted from the CR policy, either wholly or partly, relevant Ministers must obtain the agreement of the Minister for Finance and Administration.

NICNAS CRIS 04-05 Executive Summary



Australian Government
Department of Health and Ageing
NICNAS

Cost Recovery Impact Statement

A Summary of the report on cost recovery arrangements relating to the regulation of the introduction of industrial chemicals by the National Industrial Chemical (Notification and Assessment) Scheme

TGA Group of Regulators
Department of Health and Ageing
Canberra
May 2005

Executive Summary

Industrial chemicals are regulated in Australia in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS is administered as part of the Office of Chemical Safety, a business unit of the TGA Group of Regulators in the Department of Health and Ageing (the Department).

NICNAS is the national authority for the scientific assessment and management of risks to people and the environment associated with the use of industrial chemicals. Its aim is to encourage the safe and sustainable use of industrial chemicals. The principal activities of the national notification and assessment scheme include:

- Assessments of chemical risks associated with the introduction (manufacture or import) of new chemicals into Australia;
- Reviews of chemical risks associated with chemicals introduced prior to the commencement of NICNAS;
- Making assessments widely available to assist public health and environmental agencies in regulating the use, release and disposal of industrial chemicals and providing risk and safety information to industry, workers and the public;
- Ensuring compliance for inclusion in the Register of Industrial Chemicals Introducers; and
- Giving effect to international treaties.

The cost of administering NICNAS has been largely funded from industry through fees relating to new chemical assessments and from NICNAS registration fees and charges, as set out in the Act and associated Regulations. Certain activities undertaken for Government have been funded from departmental allocations or through specific service agreements. NICNAS Fees and charges account for 0.03% of the industry's \$22b turnover – these costs must be factored into commercial pricing decisions for end-user products, despite price sensitivity associated with intense industry competition from Asian imports.

	2003-04 Actual	2004-05 Estimate	2005-06 Estimate
Services	4.871	5.969	6.236
Government	0.582	0.627	0.494
Price of Outputs	5.453	6.596	6.730

In accordance with the Australian Government's cost recovery policy, cost recovery arrangements for NICNAS were reviewed to ensure they complied with Guidelines issued by the Department of Finance and Administration (DoFA). Independent consultants were engaged to review current cost recovery arrangements, consult with industry and government stakeholders and undertake an assessment of the basis for setting fees and charges.

(i)

The review found that existing cost recovery arrangements were consistent with the Guidelines and were well accepted by industry stakeholders. The level of recovery from fees and charges for new chemical assessments was in line with costs, with the variation observed attributable to fluctuations in activity levels. NICNAS registration fees and charges were sufficient to recover the cost of all other scheme activities, although some costs related to the regulation of chemicals had not been included in current cost recovery arrangements.

- The compliance program was subsidised by government funding of \$120,000 to inform and monitor small to medium enterprise compliance with the scheme. Given the extension of registration requirements in 2004 to include smaller introducers, registration fees from these companies are appropriate for funding these activities; and
- In accordance with the Guidelines, the cost of services to government that relate to the regulation of industrial chemicals and totalling around \$325,000 should be included in cost recovery arrangements. This is a change to the current cost recovery policy established in 1997 that had previously excluded these costs.

The costs of these activities are able to be met from within existing cost recovery revenues and will have no impact on existing registration fees and charges for 2005-06. NICNAS activities will therefore be funded from either industry cost recovery or specific contractual arrangements.

Stakeholder consultations were conducted with all of the major industrial chemicals industry associations, government agencies concerned with health and environmental risk assessments, and the DoFA. Whilst endorsing the principles of cost recovery, industry did not agree with the assessment that costs relating to compliance and related services to government should be included in cost recovery arrangements, nor should activities for which the primary beneficiary is the public or Government. Industry were opposed to any further fee increases and highlighted that any changes to fees needed to be planned and communicated early in full consultation with industry.

Through the Industry-Government Consultative Committee (IGCC), arrangements exist to monitor over and under-recovery. NICNAS has established an operating reserve to ensure the viability of the scheme, with any excess recoveries available for additional reform activities agreed with industry or returned to the budget to offset fees and charges (as appropriate). Cost recovery arrangements for NICNAS will be reviewed again in five years.

Terms of Reference

Review of Cost Recovery Arrangements

Objectives

The aims of the review are to:

- Ensure compliance with the Government's policy and guidelines for cost recovery for regulatory activities undertaken by NICNAS;
- Identify all costs and make sure an appropriate mechanism to recover these costs is established;
- Enable NICNAS to have the resources for efficient and effective operation;
- Ensure NICNAS has the ability to provide high quality regulatory science;
- Establish a reserve amount that allows for the continuation of business in the event there is an unexpected shortfall in estimated income;
- Develop a single cost recovery policy reference document; and
- Develop a mechanism to cost recover funds to implement recommendation 4.6 from the Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne.

Background

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 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 Cost Recovery Guidelines stipulate those agencies where total cost recovery receipts equal \$5 million or more per annum must review all cost recovery arrangements periodically, but no less frequently than every five years. The last cost recovery review for NICNAS was undertaken in 2004/05 as part of the TGA group of regulators.

Expected Outcomes

- A report on compliance with the Government's cost recovery policy for regulatory agencies;
- All costs are identified and an appropriate mechanism to recover these costs is established;
- NICNAS has the ability to continue business in the event there is an unexpected shortfall in estimated income;
- NICNAS can maintain a high quality in regulatory science and promote excellence in the workforce;
- Creation of a single cost recovery policy reference document; and
- A mechanism to cost recover funds to implement recommendation 4.6 from the Productivity Commission 2008, *Chemicals and Plastics Regulation*.

Timeframe

To commence November 2009 and be completed late 2010.

