

Appendix 2: Report from the Director of the National Industrial Chemicals Notification and Assessment Scheme on the operation of the *Industrial Chemicals (Notification and Assessment) Act 1989*

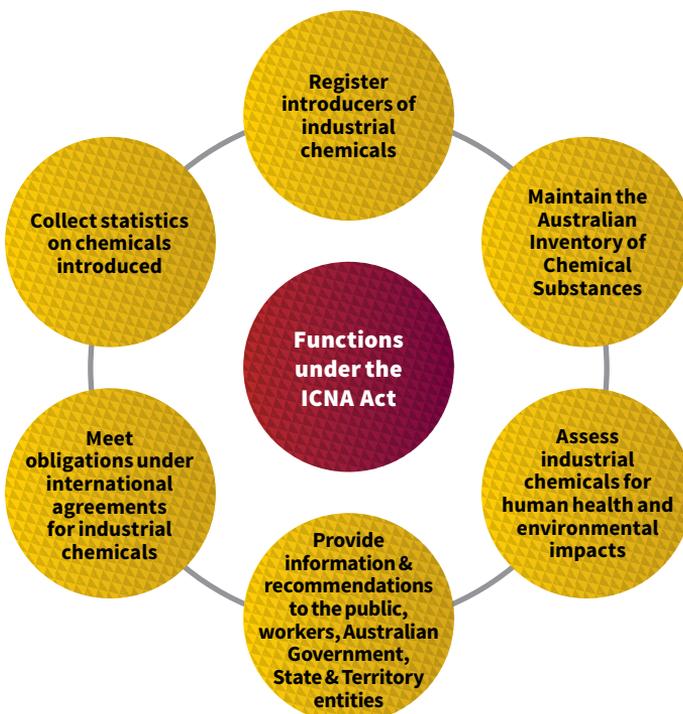


About NICNAS

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a statutory scheme established under the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act).

Under NICNAS, the risks to human health and the environment arising from the introduction (by import or manufacture) of industrial chemicals in Australia are assessed. NICNAS risk assessment reports inform State, Territory and Australian Government entities, whose combined role is to regulate the safe transport, storage, use and disposal of chemicals in Australia through a range of other legislation. Other activities conducted to support the scheme, such as registration of chemical introducers, maintenance of the Australian Inventory of Chemical Substances, and education and compliance functions, also promote the safer use of industrial chemicals. The range of NICNAS functions is illustrated in Figure 1.

Figure 1: Functions under the ICNA Act



The Director of NICNAS (the Director) is a statutory office holder appointed under the ICNA Act to independently exercise powers and functions to achieve the objects of the Act.

The Director is supported by staff in the Office of Chemical Safety (OCS) within the Department of Health, with assistance from staff in the Department of the Environment and Energy. The Director is also the Executive Director of the OCS.

In 2016-17, NICNAS:

- met all qualitative and quantitative performance criteria published in the 2016-17 Health Portfolio Budget Statements (refer *Outcome 5: Regulation, Safety and Quality*, p. 152–154 of this Annual Report);
- conducted post-market reviews of the risks of industrial chemicals already in use in Australia;
- published a report on industrial chemicals used in tattoo inks;
- launched the new NICNAS website;
- launched the new online registration portal for businesses; and
- supported the implementation of significant reforms to the scheme.

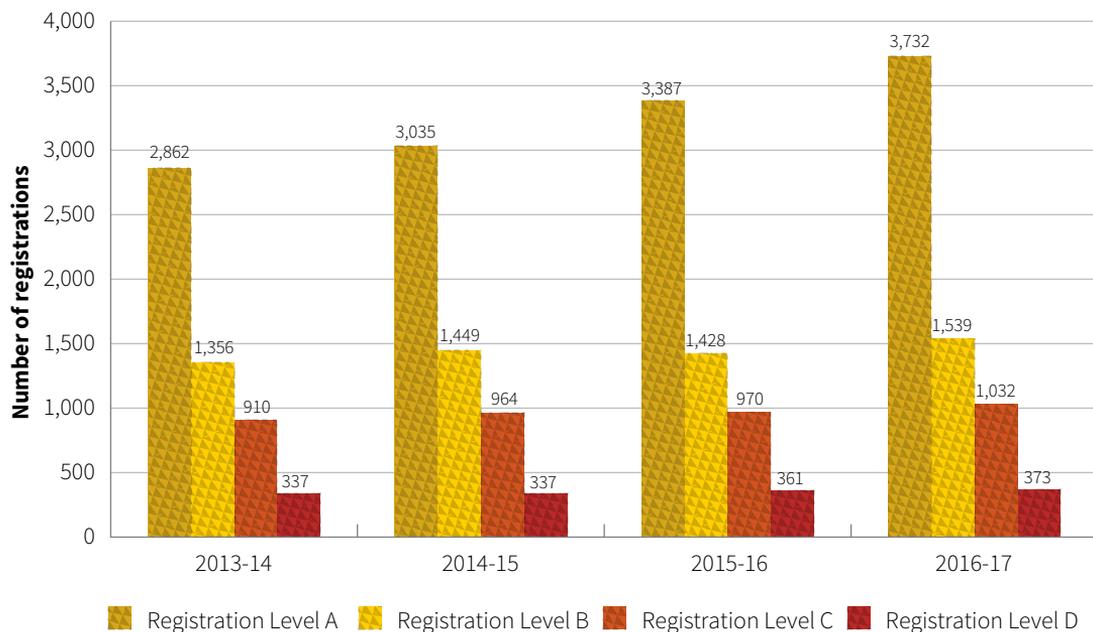
Registration of importers and/or manufacturers of industrial chemicals

Every manufacturer and/or importer (“introducer”) of industrial chemicals must be registered with NICNAS. Once registered, the introducer’s details are added to the Register of Industrial Chemical Introducers that is available on the NICNAS website.⁷⁸

Registration of introducers helps NICNAS inform industry about their legal obligations, promotes the safer use of industrial chemicals through the provision of information about chemicals, and maintains public confidence in Australia’s chemical industry.

The revenue from registration charges allows NICNAS to assess the risks of existing chemicals, as well as undertake compliance, communication and business support activities. Trends in registration are shown in Figure 2.

Figure 2: Four-year trend data for NICNAS registrations



Source: Annual Reports and internal data

⁷⁸ Available at: www.nicnas.gov.au

Key registration statistics during 2016-17

- Over 70 per cent of introducers self-registered online after the implementation of the NICNAS business portal.
- 6,676 businesses registered with NICNAS, representing the highest number of registrants in the history of the scheme.
- Decrease in manual processing of registration renewal payments from 100 per cent to less than 10 per cent as a direct result of the move to online registration.

Compliance monitoring

NICNAS's compliance monitoring activities have a strong focus on education and awareness-raising to assist introducers in understanding their obligations under the ICNA Act. These activities are supported by targeted auditing to determine an introducer's compliance with their obligations.

Key compliance statistics during 2016-17

- Over 400 registrant representatives attended awareness-raising information sessions Australia-wide.
- Over 500 new introducers registered with NICNAS as a direct result of compliance monitoring activities.
- The registration level of over 650 introducers was varied as a direct result of compliance monitoring activities.
- Over 100 new industrial chemicals requiring notification or reporting to NICNAS were identified through compliance monitoring of registered introducers.

Australian Inventory of Chemical Substances

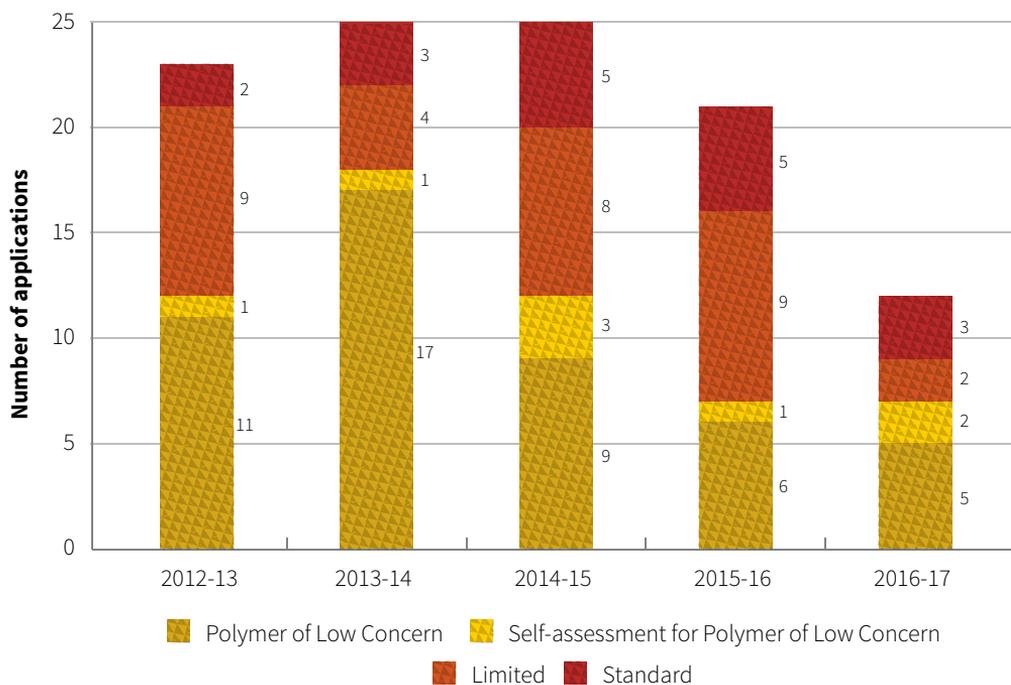
Chemicals listed on the Australian Inventory of Chemical Substances (AICS) ('existing industrial chemicals') can be introduced into Australia for any industrial purpose (in accordance with any conditions of use specified on AICS) without notification to NICNAS.

The AICS is a legal record that distinguishes 'existing' from 'new' industrial chemicals and consists of non-confidential (public) and confidential sections.

New industrial chemicals require assessment under NICNAS for risks to the environment and human health before they can be imported or manufactured, unless they are eligible for exemption from assessment under the ICNA Act. Once an assessment certificate has been issued, chemicals are listed on the AICS either five years after assessment or, upon application, can be listed on the AICS immediately.

An application for listing on the confidential section of the AICS can be made to protect the commercial interests of an introducer. Such applications are subject to a statutory test that weighs the public interest in the availability of information about the chemical against the commercial prejudice to the introducer that would result from the publication of this information. Successful applications are reviewed after five years, with re-application of the statutory public interest test.

Figure 3 shows trends in confidential listing applications over recent years.

Figure 3: The original assessment categories for confidential listing applications from 2012-13 to 2016-17

Source: NICNAS internal data

In 2016-17, industry was requested to provide NICNAS with information on the chemical identity (Chemical Abstracts Index name, Chemical Abstracts Service number and molecular formula) of all industrial chemicals making up products listed in the Trade Name Annex (TNA) of the AICS. Provisions under the ICNA Act allow for the removal of products from the TNA and the addition of their constituents to the AICS without assessment. Information was requested on 7 March 2017, to be submitted to NICNAS within one year.

Key AICS statistics for the year ending 30 June 2017

- 40,286 chemicals were on the public AICS, with 98 chemicals on the confidential AICS.
- 127 chemicals for which an assessment certificate had been issued five years previously were due to transfer to the public AICS.
- The number of applications for listing on the confidential AICS had declined over the previous three years (Figure 3). Of the 12 applications for confidential listing received and approved, seven applications were for Polymers of Low Concern (PLCs) (two self-assessed as PLCs and five PLCs assessed under NICNAS).
- 243 requests were received from bona fide introducers for a search of the confidential section of the AICS.
- 124 inquiries were received in response to the call for information on products in the TNA section of the AICS, and information on 18 products (containing 44 chemicals) was submitted.

New imported and/or manufactured industrial chemicals

Any chemical that is not listed on the AICS, or is listed on the AICS but proposed for a use outside the conditions prescribed on the AICS, or is ineligible for exemption under the ICNA Act, must be notified for assessment under NICNAS. Permits and certificates are issued after risks to human health and the environment from a chemical are assessed and are required prior to manufacture or importation of the chemical into Australia.

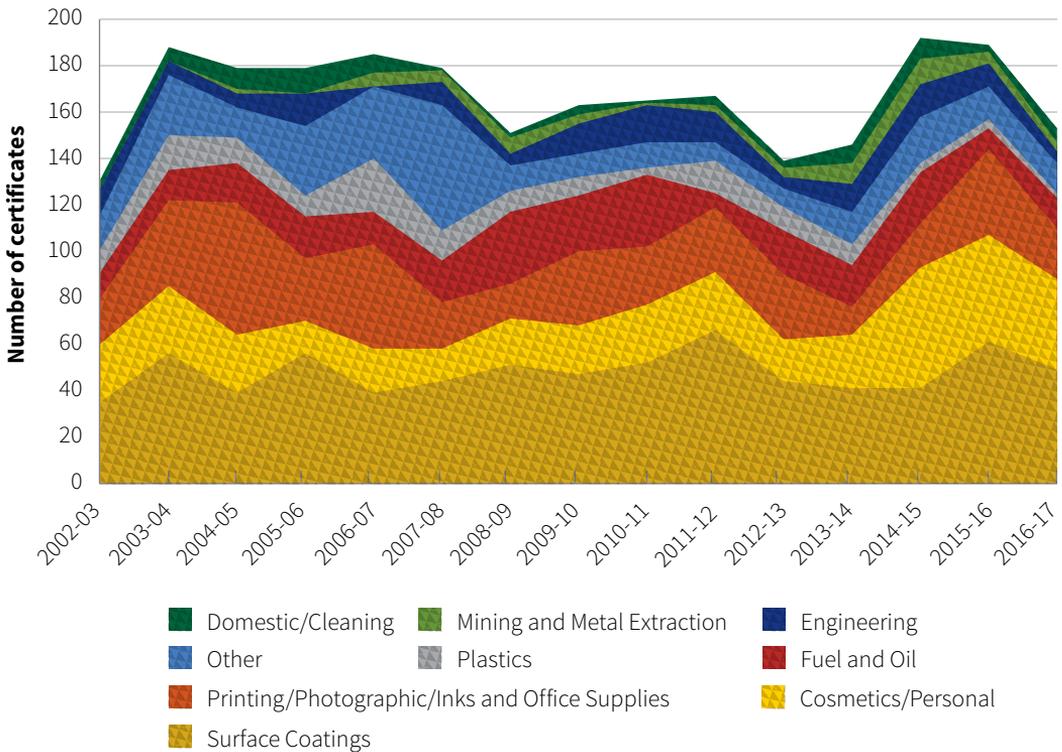
Figures 4, 5 and 6 describe trends in the assessment of new chemicals notified by industry.

Figure 4: Certificates and permits issued 2002-03 to 2016-17

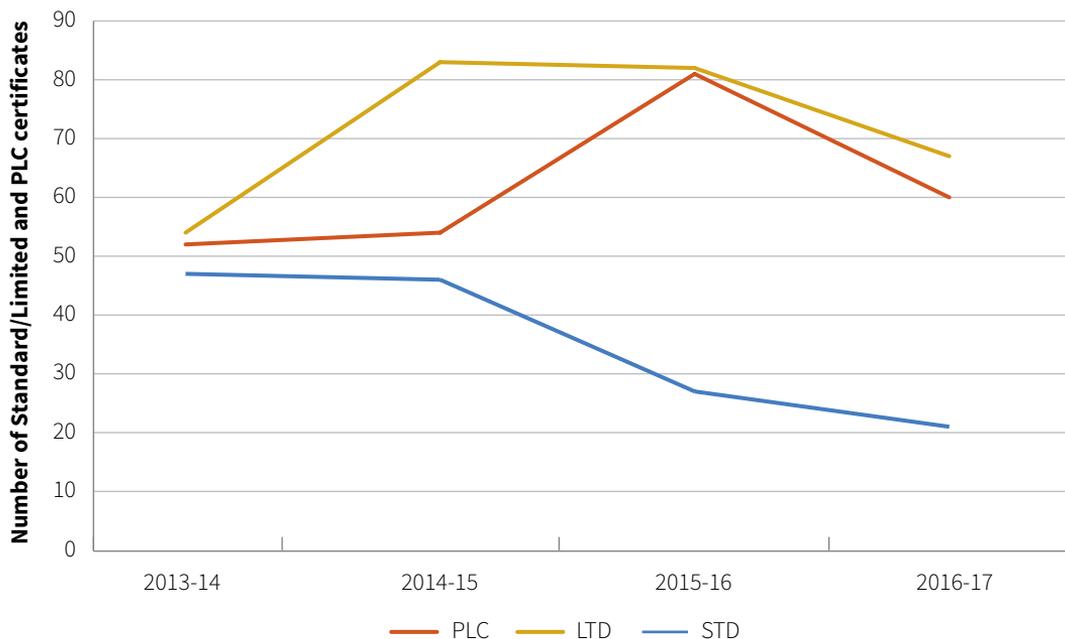


Source: NICNAS internal data

Figure 5: Standard, Limited and Polymer of Low Concern Certificates issued by use category from 2002-03 to 2016-17



Note: The area displays trends over time and are stacked so that each series adjoins but does not overlap the preceding series.
 Source: Annual Reports and internal data

Figure 6: Standard, Limited and Polymer of Low Concern Certificates issued from 2013-14 to 2016-17

Source: Annual Reports and internal data

Key statistics for new industrial chemicals for the year ending 30 June 2017

- 276 certificates and permits for new industrial chemicals were issued during the year.
- 10,150 industrial chemicals were reported as being introduced under exemption categories by 217 introducers.

Assessment of existing industrial chemicals

Inventory Multi-Tiered Assessment and Prioritisation (IMAP) framework

The IMAP framework consists of three tiers of chemical assessment, with the assessment effort increasing with each tier. The aim is to provide more timely information about the hazards and risks associated with the use of industrial chemicals by identifying chemicals which:

- pose no unreasonable risk to human health or the environment (Tier I);
- require human health or environmental risk management measures to be instituted for safe use (Tier II); and
- require more in-depth assessment to fully determine its impact on human health and/or the environment (Tier III).

Implementation of Stage Two of the IMAP framework began 1 July 2016. Based on the findings of a review of IMAP Stage One (2012–2016), the framework has been refined, including by identifying and de-prioritising chemicals of low regulatory concern, adjusting mechanisms for prioritising chemicals of concern, establishing alternative information-gathering mechanisms for ‘data-poor’ chemicals, and implementing new architecture (databases/networks) for conducting assessments electronically. These refinements enabled NICNAS to significantly increase the number of assessments conducted using the IMAP framework.

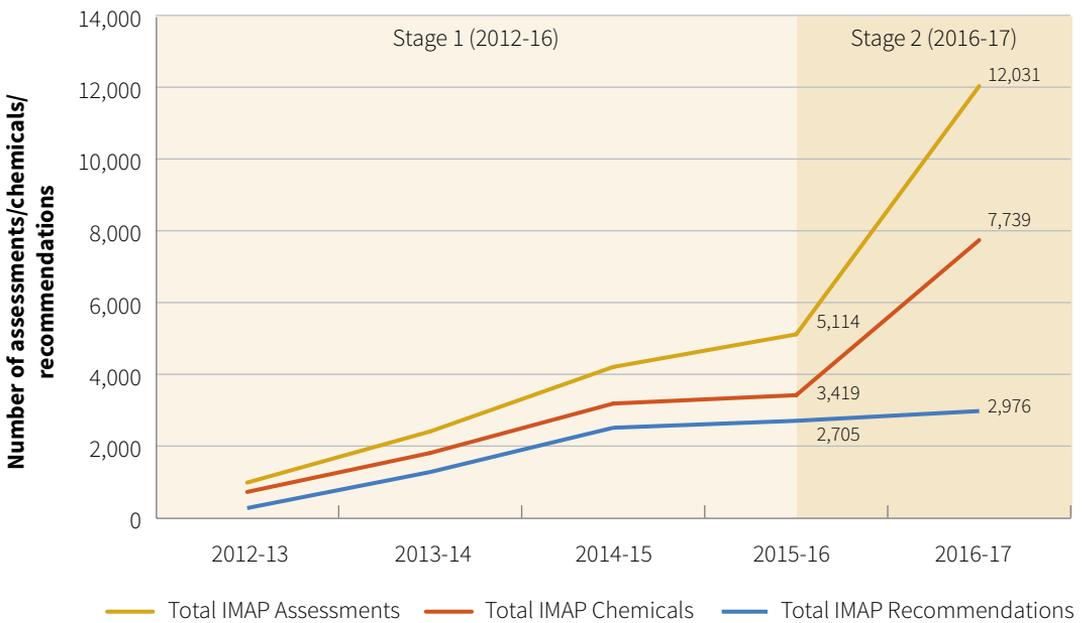
Information on the potential risks associated with the use of chemicals assessed using the IMAP framework is provided to international regulatory authorities and local risk management agencies. Collaboration with a range of international and local counterparts, industry bodies and community groups ensured that evidence to support the recommendations was available.

IMAP Stage Two includes consideration of a large number of chemicals that posed a low risk to human health or the environment (Tier I assessments). This assessment approach balances the assessment pace with the impact on stakeholders. Tools and approaches developed during Stage Two enabled NICNAS to gain efficiencies in the screening of chemicals on the AICS. The large increase in chemicals published at Tier I was focused on chemicals with excluded non-industrial uses, low concern polymers, substances derived from natural products, plant extracts used in low volumes and chemicals identified as low concern to human health by the application of expert validation rules. The identification of low risk chemicals in Stage Two is consistent with international best practice, provides valuable information to stakeholders and contributes to preparatory (pre-prioritisation) work to identify criteria for the identification of higher risk chemicals requiring assessment.

Improvements in assessment methods and processes developed for IMAP Stage Two will contribute to the ongoing assessment of chemicals already in commerce that is planned as part of reforms to NICNAS.

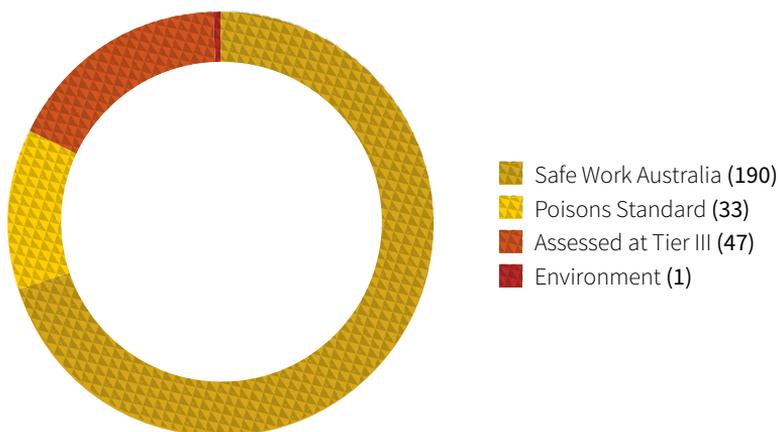
The outcomes of IMAP Stages One and Two are illustrated in Figures 7 and 8 and Table 1.

Figure 7: Outcomes of IMAP Stages One and Two, years 1-5



Source: Annual Reports and internal data

Figure 8: Total recommendations from IMAP Stage Two



Source: Annual Reports and internal data

Table 1: Cumulative (Tier I, II, III) assessments in Stage One and Stage Two

	Stage One (2012–16) (Tranches 1–18)	Stage Two (2016–17) (Tranches 19–21)
Tier III	11	5
Tier II	2,731	302
Tier I	2,372	6,610
Total assessments	5,114	6,917

Source: Annual Reports and internal data

Key existing chemical assessment statistics during 2016-17

- 6,917 human health and environment assessments for 4,367 unique industrial chemicals (compared to the previous year's (2015-16) total of 909 assessments).
- A total of 6,610 Tier I assessments.
- 271 recommendations to manage newly identified risks associated with the industrial use of 223 unique chemicals.

Secondary notification assessments

When new information or other changed circumstances warrant re-assessment of a chemical previously assessed by NICNAS, introducers of the chemical must provide further information to NICNAS, in a process known as secondary notification.

Key secondary notification assessment statistics during 2016-17

- One Secondary Notification assessment report was published.
- One draft report of a Secondary Notification was provided to applicants.
- Two Secondary Notifications were declared (one for a new chemical and one for an existing chemical).

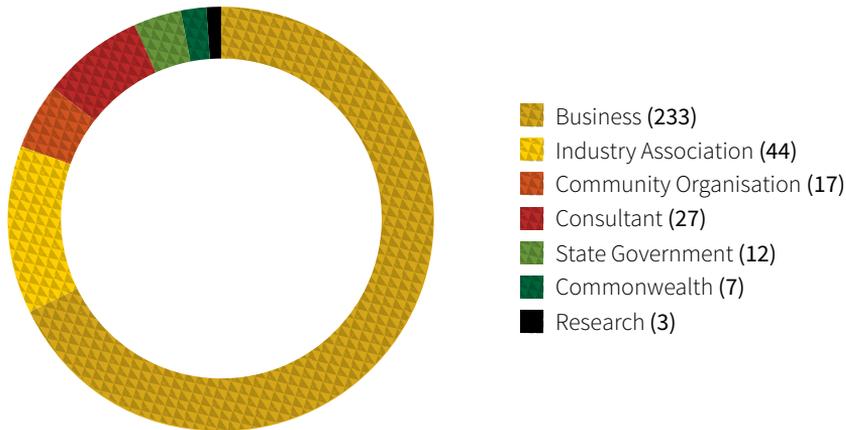
NICNAS reforms

As announced in the 2015-16 Budget, significant reforms to the scheme are expected to commence from 1 July 2018.

Details supporting the implementation of these reforms have been developed through a series of government reviews and extensive consultation with industry, community, Australian Government and State and Territory Government stakeholders.

Figure 9 describes aspects of the stakeholder consultation for the NICNAS Reforms.

Figure 9: Groups registered to receive information on the NICNAS Reforms



Source: NICNAS internal data

Key NICNAS reform statistics for 2016-17

- The last of four consultation papers on matters to be included in the primary legislation and one technical consultation paper on matters to be included in delegated legislation were published. Public workshops were held during the consultation period in each case, attended by over 170 stakeholders.
- Over 300 individual stakeholders from community, industry and Government entities specifically requested further information on the NICNAS Reforms.
- An ad-hoc working group of technical experts provided additional advice on the implementation of the reforms.
- A discussion paper on the Cost Recovery Model to support the reformed scheme was published.

Stakeholder consultation

The NICNAS Strategic Consultative Committee (SCC), with representatives from peak industry and community groups, met on two occasions (October 2016 and March 2017) to provide strategic advice to the Director on efficiently achieving the objectives of the ICNA Act and development of the NICNAS reforms. As the external validation body for NICNAS under the Regulator Performance Framework (RPF), the SCC validated NICNAS's self-assessment report under this framework.

The SCC was consulted in advance of the publication of the two consultation papers on the NICNAS reforms. A summary of outcomes of SCC meetings is published on the NICNAS website.⁷⁹

⁷⁹ Available at: www.nicnas.gov.au/about-us/advisory-groups/strategic-consultative-committee

The SCC also discussed:

- NICNAS regulatory and financial performance.
- Options for managing confidential information supplied by a third party when secondary notification of a chemical is required.
- Transition approaches for the NICNAS Existing Chemicals Program to the reformed scheme.
- The AICS Trade Names Annex.
- Establishment of a technical working group to provide scientific advice on matters relating to categorisation and assessment prior to further public consultation on delegated legislation.

Digital services

The redeveloped and upgraded NICNAS website was launched in 2016-17 with improved navigation, usability, search performance and design. All new site content meets the Web Content Accessibility Guidelines (WCAG) 2.0 accessibility guidelines and the Australian Digital Service Standard, which includes a shift towards plain English content.

International engagement

NICNAS staff administering actively collaborated with international counterparts through a variety of fora. The Organisation for Economic Co-operation and Development Chemicals Committee and its key subsidiary committees are the principal mechanisms through which NICNAS staff engage multilaterally. Formal bilateral memoranda of understanding are in place with counterparts in Europe, United States, Canada and New Zealand. NICNAS staff also actively contribute to the work of the Asia-Pacific Economic Cooperation Chemical Dialogue. International collaboration facilitates access to scientific expertise, assessment tools and methodologies, benefiting NICNAS and promoting international harmonisation of regulatory requirements. International engagement has been particularly valuable in developing the implementation detail of the reforms.

Staff development

The OCS Learning Centre, a cloud based system with an online Toxicology Course, was launched in 2017 to maintain the high level of scientific rigour in the risk assessment of industrial chemicals.

Financial performance

Compared with 2015-16, total revenue and expenses have increased by \$0.887 million and \$0.9 million, respectively.

Revenue recovered from the regulated industry was \$17.4 million, which is \$1.1 million higher than the previous year due to a 9 per cent increase in the number of registrants.

Net revenue from other sources was \$0.3 million, which is \$0.2 million lower than the previous year, due a reduction in externally-funded projects.

Total expenses were \$15.5 million, which is \$0.9 million higher than the previous year. This result is due to operational costs associated with the increase in reform-related activities in 2016-17.

As shown in Table 2, the NICNAS final net result for 2016-17 was a surplus of \$2.2 million which will be maintained in the NICNAS Special Account. Funds in the Special Account will provide for business continuity requirements, future capital projects and to fund the resources required to finalise the delegated legislation, cost recovery arrangements, technical guidance materials and tools, in preparation for implementation of the new scheme on 1 July 2018.

Table 2: Five year comparison of NICNAS revenue and expenses

	2012-13 \$'000	2013-14 \$'000	2014-15 \$'000	2015-16 \$'000	2016-17 \$'000
Industry cost recovered revenue	11,089	12,819	13,045	16,324	17,383
Other revenue	2,809	2,094	1,023	493	321
Total revenue	13,898	14,913	14,068	16,817	17,704
Total expenses	13,074	13,906	13,764	14,602	15,502
Operating surplus/(deficit)	824	1,007	304	2,215	2,202

Acknowledgements

I would like to acknowledge the hard work and dedication of staff in both the Department of Health and the Department of the Environment and Energy, who have contributed not only to the efficient operation of the current scheme during 2016-17, but also to the development of the new scheme to replace NICNAS from July 2018.

I have appreciated the strategic advice that I have received from members of the NICNAS Strategic Consultative Committee and the technical input from members of the ad hoc working party supporting the NICNAS reforms.

In addition, I would like to thank a range of other industry and community stakeholders, as well as staff from other Australian Government, State and Territory entities who have also made important contributions to the effective regulation of industrial chemicals in Australia.

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