

Appendix 2

Report from the Director of the National Industrial Chemicals Notification and Assessment Scheme

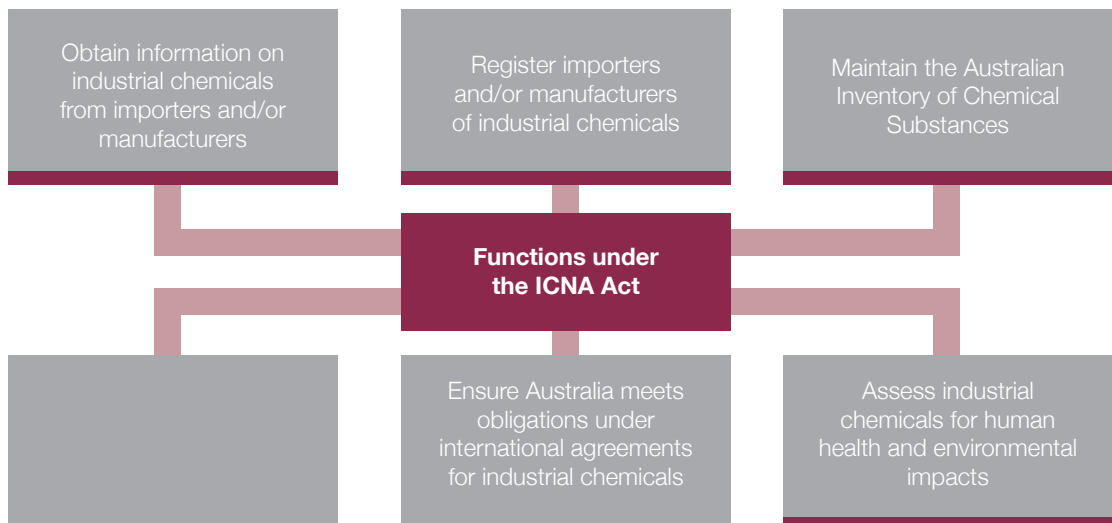
About NICNAS

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act). The scheme aids in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use.

NICNAS assessment reports are used by a range of Government entities that regulate the control, use, release and disposal of industrial chemicals. NICNAS also informs workers, industry and the community about the safe use of industrial chemicals.

NICNAS achieved all of its key performance targets for 2015-16 within the available budget, as detailed in Part 2.1: *2015-16 Annual Performance Statements*, pages 153–158.

Figure 1: Description of functions under the ICNA Act



Registration of importers and/or manufacturers of industrial chemicals

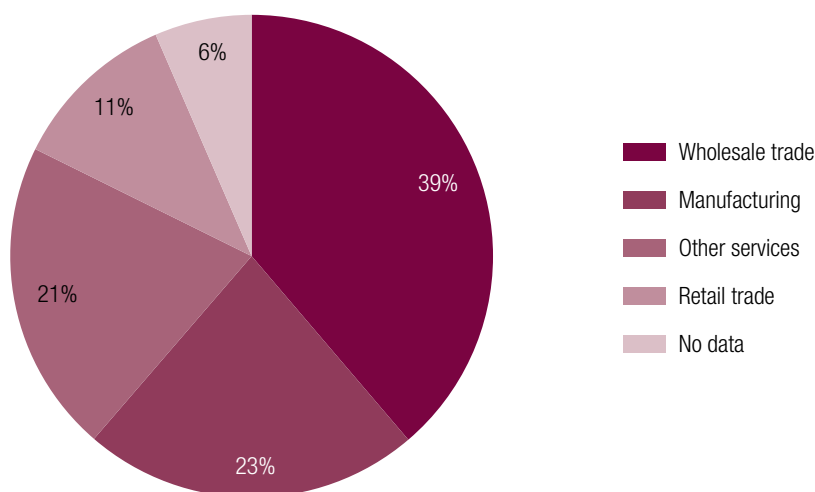
The registration of importers and/or manufacturers of industrial chemicals helps NICNAS to monitor the introduction of industrial chemicals in Australia, communicate effectively with the regulated industry and maintain public confidence that the chemical industry is aware of and complying with its regulatory obligations.

There are four different registration levels (Levels A to D) with levies for each level set according to the value of relevant industrial chemicals introduced.

Key registration statistics during 2015-16:

- 6,144 businesses were registered with NICNAS.
- Over 300 new businesses registered as a result of compliance monitoring activities.
- More than 600 people attended 13 NICNAS education and outreach sessions.

Figure 2: Registered businesses by industry sector (2015-16)



Source: NICNAS internal data

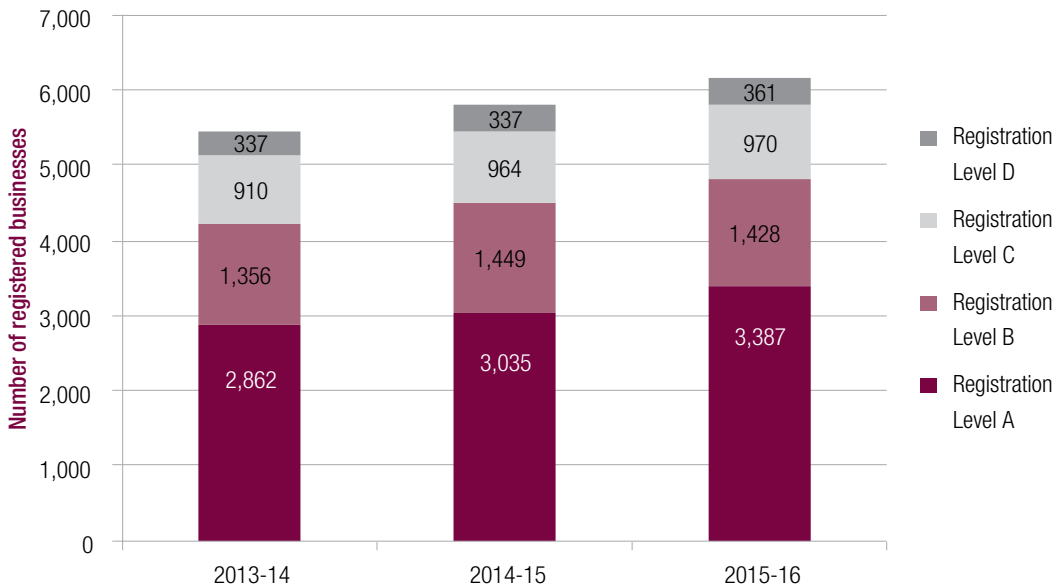
Compliance monitoring

NICNAS undertakes a range of compliance monitoring activities to assist importers and manufacturers of industrial chemicals to be aware of and comply with their obligations under the ICNA Act.

Key compliance statistics during 2015-16:

- 45% of all high volume importers and/or manufacturers were surveyed, with 55 businesses required to provide further information to NICNAS for potential non-compliance.
- 80 cases of potential non-compliance were identified, with 54 cases resolved within the financial year.
- As a result of resolved non-compliance:
 - 12 new industrial chemicals were notified or reported.
 - Introduction of 8 chemicals ceased.

Figure 3: Three-year trend data for NICNAS registrations



Source: NICNAS Annual Reports and internal data

Australian Inventory of Chemical Substances

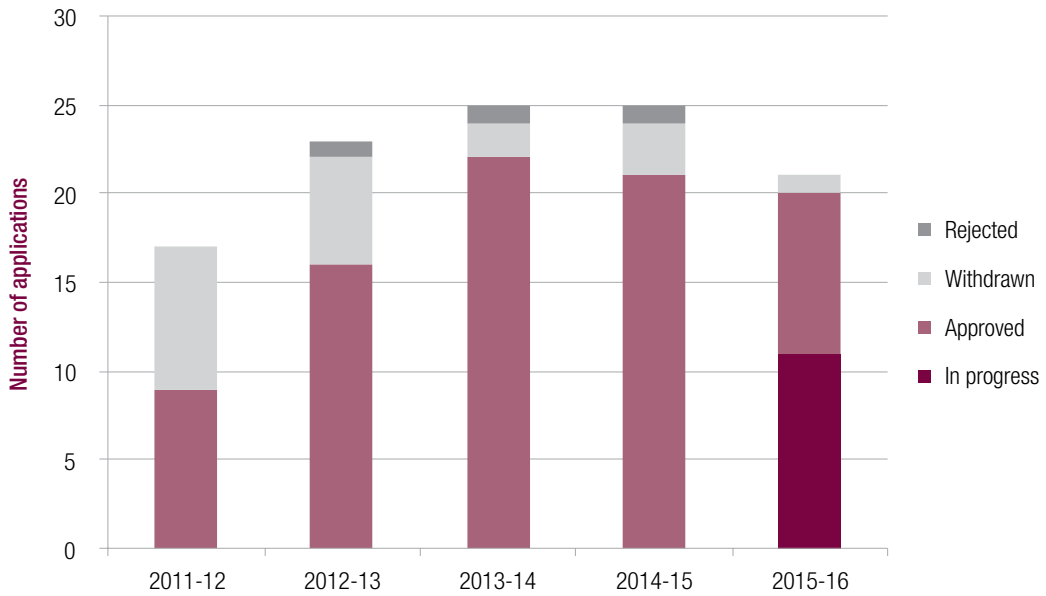
The Australian Inventory of Chemical Substances (AICS) lists industrial chemicals that may be manufactured and/or imported in Australia without notification to NICNAS. Chemicals on the AICS are known as 'existing' industrial chemicals. If a chemical is not listed on the AICS, it is considered to be a 'new' industrial chemical. New industrial chemicals assessed by NICNAS are listed on the AICS five years after an assessment certificate has been issued.

The AICS consists of a non-confidential (public) and confidential section. Applications for confidential listing are subject to a statutory public interest test. A chemical that satisfies this test is listed on the confidential AICS for five years, after which time the chemical is transferred to the public AICS unless another application is received, which again satisfies the public interest test.

Key AICS statistics during 2015-16:

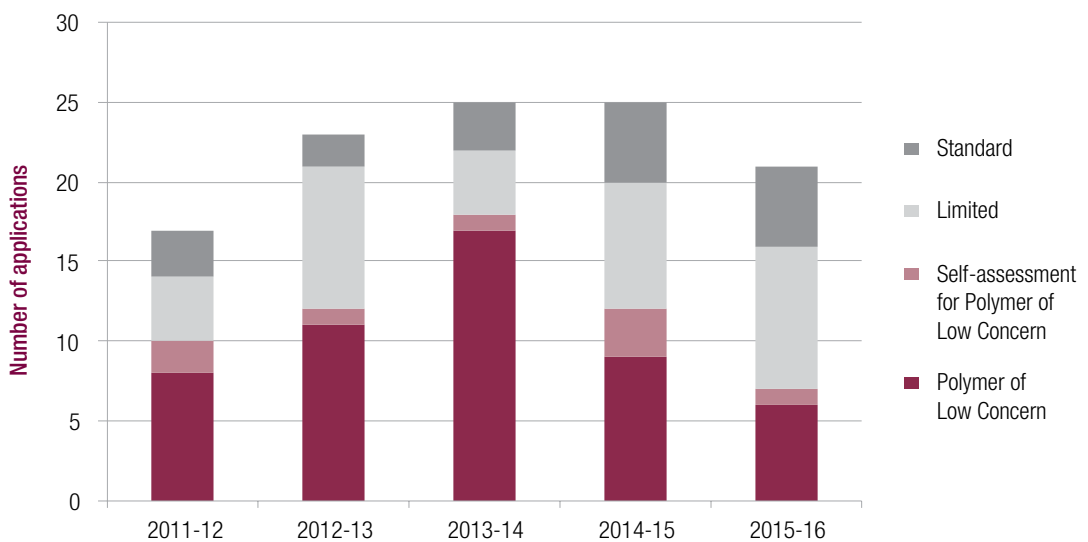
- 40,061 chemicals were on the public AICS, with 81 chemicals on the confidential AICS.
- 138 chemicals for which an assessment certificate had been issued five years previously, or had been listed on the confidential AICS for five years, were due to transfer to the public AICS.
- 21 of these chemicals were considered for confidential listing/re-listing; nine chemicals were approved for confidential listing, one was withdrawn by the applicant and 11 remained under consideration at the end of the financial year.
- 56% of approved applications for confidential listing were for polymers of low concern.
- 222 requests were received from bona fide introducers for a search of the confidential section of the AICS.

Figure 4: Outcomes of applications for confidential listing on the AICS received from 2011-12 to 2015-16



Source: NICNAS internal data

Figure 5: The original assessment categories for confidential listing applications from 2011-12 to 2015-16



Source: NICNAS internal data

New imported and/or manufactured industrial chemicals

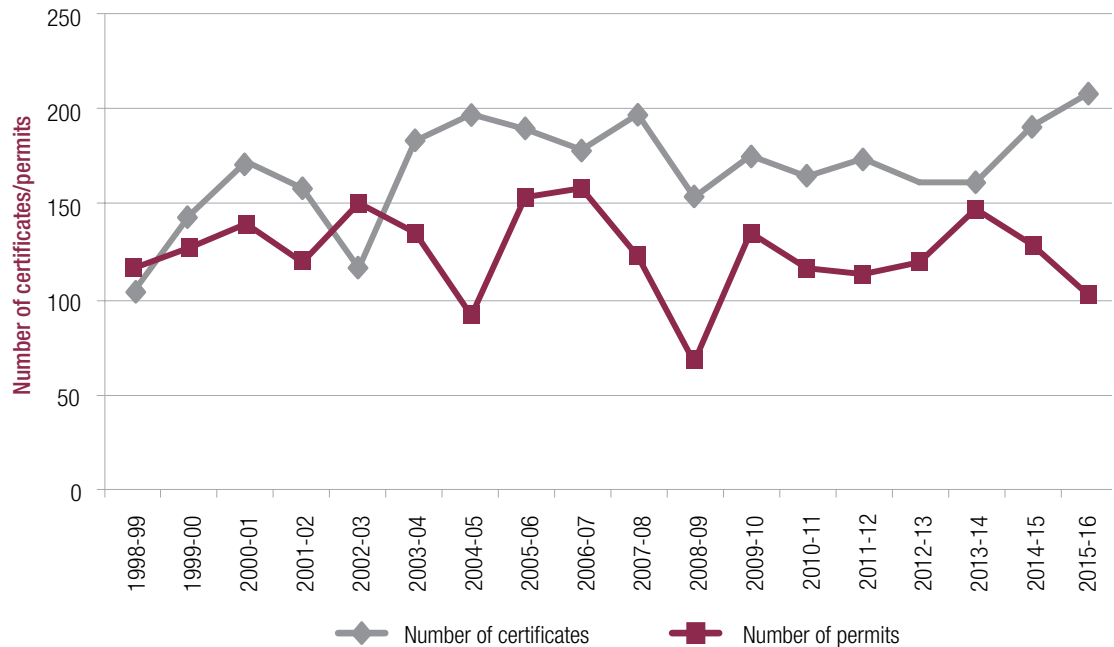
Unless a chemical is eligible under the ICNA Act for an exemption, all new industrial chemicals must be notified for assessment by NICNAS for risks to human health and the environment before they can be manufactured or imported into Australia. NICNAS assessments of new industrial chemicals lead to the issuing of permits and certificates. Chemicals introduced under a permit are not eligible for listing on AICS.

Key assessment statistics during 2015-16:

- 11,688 new industrial chemicals introduced under exemptions were reported by 208 introducers.
- 311 new industrial chemicals were assessed prior to introduction into Australia.

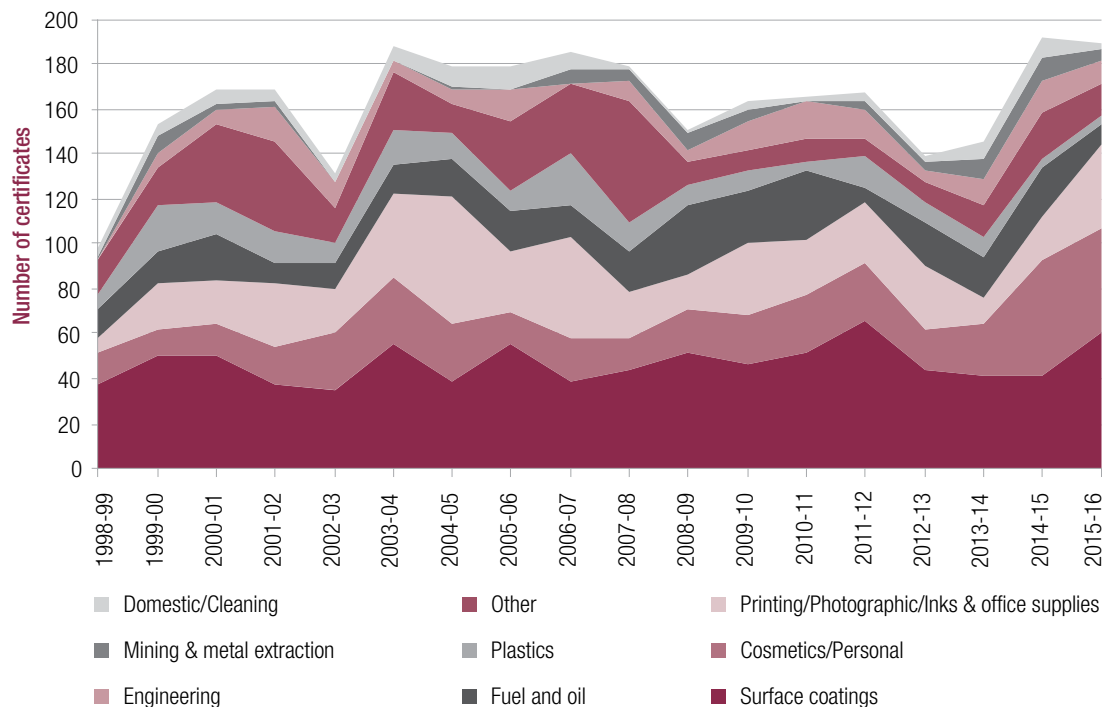
The following figures describe trends in the assessment of new chemicals notified by industry:

Figure 6: Certificates and permits issued 1998-99 to 2015-16



Source: NICNAS Annual Reports and internal data

Figure 7: Standard, Limited and Polymer of Low Concern Certificates issued by use category from 1998-99 to 2015-16



Note: The areas display trends over time and are stacked so that each series adjoins but does not overlap the preceding series.

Source: NICNAS Annual Reports and internal data

Assessment of existing industrial chemicals

On 30 June 2016, NICNAS completed Stage One of the application of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, which had commenced 1 July 2012. The application of the IMAP framework increased the availability of chemical safety information, leading to improved advice to risk management agencies about the measures that should be undertaken to help protect the Australian people and the environment.

By 30 June 2016, NICNAS had completed 5,114 human health and environment assessments for 3,419 unique industrial chemicals, exceeding the target of 2,850 chemicals set at the start of the program (95 per cent of the 3,000 chemicals prioritised for assessment in Stage One). This total includes 909 assessments completed in 2015-16. Greater program efficiency was gained by assessing 515 chemicals that were not included on the Stage One list, due to chemical similarities with other chemicals under assessment.

2,705 recommendations for 2,135 unique chemicals (including 194 for 2015-16) were identified for risk management or further assessment by NICNAS. NICNAS collaborated with its international counterparts, Australian risk management agencies (such as Safe Work Australia, the Chemicals Scheduling Delegate for the Poisons Standard and the Australian Competition and Consumer Commission), industry bodies and community groups to enable accurate and relevant information to be considered in undertaking IMAP assessments.

1,019 chemicals were recommended for classification for carcinogenicity, mutagenicity or toxicity to reproduction (CMR) – 71 per cent of these chemicals did not have equivalent classification overseas. 258 new entries or amendments to the Poisons Standard were recommended, with 40 per cent now aligned with international regulatory authorities. No direct equivalent restriction internationally was available for the remainder.

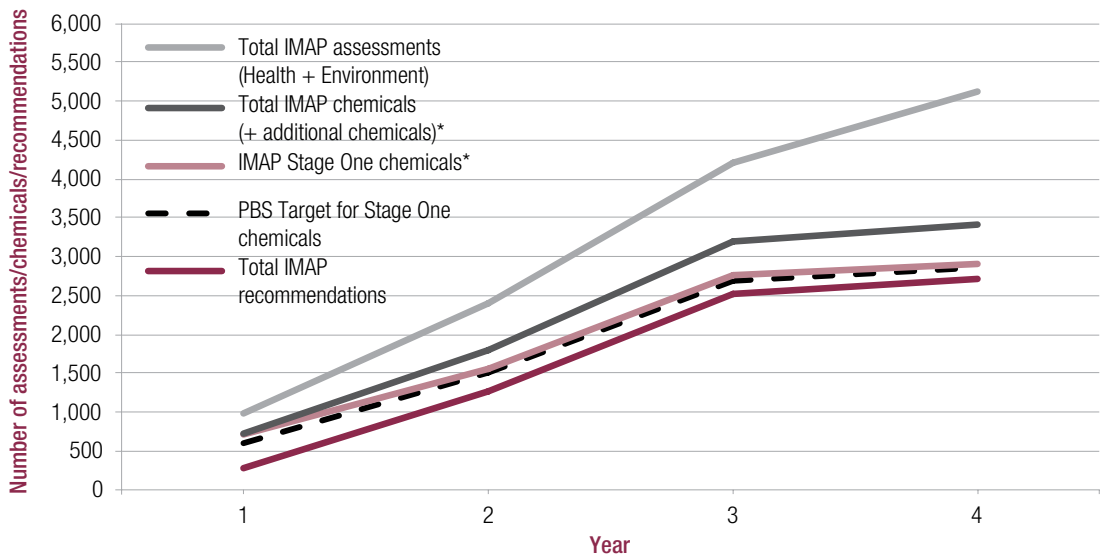
A six-to-eight week public comment period after the publication of each tranche of assessment reports enabled the provision of further information that added important value to the assessment reports.

A review of Stage One of the IMAP framework was completed in 2016, which identified opportunities to enhance the IMAP framework and adapt it to support assessments under the NICNAS reforms. The outcomes of the review have been published on the NICNAS website.¹⁰⁹

IMAP review findings:

- The IMAP framework is very effective in accelerating high quality assessment outputs for existing chemicals.
- Tools and approaches used in the IMAP framework are aligned with international best practice and are fit for purpose.
- Data from international sources are fundamental to IMAP's success. Significant diversity in the scope of international data demonstrated the important role of the framework in identifying potential risks associated with the use of industrial chemicals in Australia.

Figure 8: Outcomes of IMAP Stage One



*Assessed for human health and/or environment

Source: NICNAS Annual Reports, internal data and 2015-16 Health Portfolio Budget Statements

NICNAS reforms

The reforms to NICNAS aim to streamline assessment processes, focus regulatory effort on higher risk chemicals, and maintain Australia's robust health, safety and environmental standards.

The implementation of the reforms is being developed in consultation with industry, community and government stakeholders.

Stakeholder views will be considered in finalising the regulatory model submitted to Government for introduction into Parliament, with a view to full implementation by July 2018.

¹⁰⁹ Available at: www.nicnas.gov.au/chemical-information/imap-assessments/imap-review-2016

Key NICNAS reform statistics during 2015-16:

- Three public consultation papers were released, with 119 written submissions received in response.
- Over 300 people attended six stakeholder workshops.
- Over 100 organisations were consulted.

Stakeholder advice

The NICNAS Strategic Consultative Committee (SCC) first met in August 2015. The SCC has representation from peak industry and community groups, is chaired by the Director of NICNAS, and its membership and Terms of Reference were approved by the (then) Assistant Minister for Health.

The SCC held four meetings in 2015-16 (August, November, March and May), and two working groups were convened to consider the approaches proposed under the NICNAS reforms to introduce new chemicals at a concentration of up to one per cent in formulated products, and to implement transitional arrangements.

The SCC was consulted in advance of the publication of the three consultation papers describing the proposed approach to implementing the NICNAS reforms. The Committee also discussed:

- the management of Confidential Commercial Information by NICNAS;
- chemicals introduced under exemptions from notification and assessment;
- tattoo inks;
- the review of the IMAP framework;
- NICNAS involvement in the Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials; and
- NICNAS regulatory and financial performance results.

Digital services

A review of the NICNAS website was completed in 2015-16 to explore options for improving navigation, usability and design. An upgrade of the website's search engine saw the introduction of an improved search results display and ability to search both the AICS and website content.

International engagement

NICNAS contributes to and benefits from international collaboration through increased understanding and agreement on international risk assessment approaches, principles and practices.

In 2015-16, NICNAS maintained its active engagement with trusted international regulators. The OECD Chemicals Committee and its key subsidiary committees are the main mechanisms through which NICNAS engages multilaterally.

Engagement with regional jurisdictions through the Asia Pacific Economic Cooperation Chemical Dialogue continued. Ongoing dialogue between NICNAS and its Canadian, European and US counterparts through existing cooperative arrangements was valuable, as this facilitated access to scientific expertise, assessment tools and methodologies, enabling Australian industrial chemicals regulation to remain at world's best practice.

Financial performance

Table 1: Five year comparison of NICNAS revenue and expenses

	2011-12 \$'000	2012-13 \$'000	2013-14 \$'000	2014-15 \$'000	2015-16 \$'000
Industry cost recovered revenue	9,014	11,089	12,819	13,045	16,324
Other revenue	836	2,809	2,094	1,023	493
Total revenue	9,850	13,898	14,913	14,068	16,817
Total expenses	10,004	13,074	13,906	13,764	14,602
Operating surplus/(deficit)	(154)	824	1,007	304	2,215

Compared with 2014-15, total revenue and expenses have increased by \$2.749 million and \$0.838 million, respectively.

Industry cost recovered revenue was \$16.324 million, which is \$3.279 million higher than the previous year. 2015-16 revenue was affected by changes to registration fees and charges, which were increased to fund the implementation of the NICNAS reforms in accordance with the NICNAS Cost Recovery Implementation Statement.

Net revenue from other sources was \$0.493 million, which is \$0.530 million lower than the previous year, due to the completion of an external project.

Total expenses were \$14,602 million, which is \$0.838 million higher than the previous year. This result is due to operational costs associated with the NICNAS reforms, net of a \$0.502 million decrease in costs of an external project.

The NICNAS final net result for 2015-16 was a surplus of \$2.215 million, which will be retained in the NICNAS Special Account to provide for business continuity requirements, future capital projects and to fund staff entitlements, in accordance with relevant Government policies.

Acknowledgements

NICNAS is administered by highly skilled and dedicated staff in both the Department of Health and the Department of the Environment and Energy, with advice from the NICNAS Strategic Consultative Committee and its working groups. Many stakeholders provided thoughtful and constructive input into the implementation of the reforms to NICNAS that were announced in the context of the 2015-16 Budget. I sincerely appreciate the efforts of staff and stakeholders in the work of the scheme.

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