



**Australian Government**

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**Department of Health**

National Industrial Chemicals  
Notification and Assessment Scheme

# **National Industrial Chemicals Notification and Assessment Scheme**

## **Regulator Performance Framework Self-Assessment Report 2015-16**

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## Glossary

<b>Acronyms</b>	<b>Description</b>
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>APEC</b>	Asia Pacific Economic Cooperation
<b>ICNA Act</b>	Industrial Chemicals (Notification and Assessment) Act 1989
<b>IMAP</b>	Inventory Multi-tiered Assessment and Prioritisation
<b>IATA</b>	Integrated Approach to Testing & Assessment
<b>Level C registrants</b>	Introduction value from \$500,000-\$4,999,999
<b>Level D registrants</b>	Introduction value of \$5,000,000+
<b>Nett Agree</b>	total percentage of survey respondents who agreed or strongly agreed with survey statement/proposition
<b>Nett Disagree</b>	total percentage of survey respondents who disagreed or strongly disagreed with survey statement/preposition
<b>NICNAS</b>	The National Industrial Chemicals Notification and Assessment Scheme
<b>OCS</b>	Office of Chemical Safety
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>PEC</b>	Priority Existing Chemical
<b>QSAR</b>	Quantitative structure-activity relationship
<b>RPF</b>	Regulator Performance Framework
<b>SCC</b>	Strategic Consultative Committee
<b>UNEP</b>	United Nations Environment Program

# **1 INTRODUCTION**

## **1.1 National Industrial Chemicals Notification and Assessment Scheme**

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is established under the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) and is administered by the Office of Chemical Safety (OCS) within the Department of Health. NICNAS aids in the protection of the Australian people and the environment by assessing the risks of industrial chemicals. NICNAS assessments inform decisions made by a wide range of Commonwealth, state and territory government agencies involved in regulating the control, use, release and disposal of industrial chemicals.

As part of the 2015-16 Budget, the Australian Government announced a range of reforms to the regulation of industrial chemicals so that the assessment effort would be more proportionate to the risks posed by industrial chemicals, while also maintaining Australia's robust health and safety standards.

An important benefit of realigning regulatory effort towards chemicals with a higher risk profile is that the costs to businesses and consumers using lower risk chemicals will be reduced. The faster regulatory pathway to introduction of lower risk chemicals provides an incentive to introduce safer new industrial chemicals, including replacing more hazardous existing chemicals. A greater focus on post-market assessment and monitoring will assist in maintaining the protection of health and safety of consumers, workers and the environment.

## **1.2 The Regulator Performance Framework**

In October 2014, the Australian Government developed a framework to measure the performance of regulators which strives to reduce the cost of unnecessary or inefficient regulation imposed on industry and, by measuring and publicly reporting on performance, and giving confidence that regulators effectively and flexibly manage risk.

OCS developed metrics to demonstrate performance against key performance indicators specified in the RPF, in consultation with the NICNAS [Strategic Consultative Committee](#) (SCC), comprised of representatives from peak national stakeholder groups, which is responsible for validating this report.

## **1.3 Methodology**

The evidence presented in this report is obtained from performance statistics collected by OCS throughout the 2015-16 financial year, including information reported in the 2015-16 Department of Health Annual Report. OCS also commissioned the Department of Health's Market Research Unit to undertake an online stakeholder survey. The final methodology for the survey, including the questionnaire, was approved by the Australian Bureau of Statistics Statistical Clearing House.

The survey was open from 9 June 2016 until 1 July 2016. 6,057 NICNAS registrants and recipients of NICNAS newsletters and the Chemical Gazette were invited to log in to an online survey and provide feedback across a range of service areas. A total of 934 valid responses were received. Survey results were analysed and reported by the Market Research Unit.

## 2 Performance Assessment

### 2.1 KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities

#### 2.1.1 Measures of good regulatory performance – Demonstrated understanding of the operating environment of regulated entities

2015-16 evidence	Self-assessment
<p>NICNAS regularly engages with stakeholders to maintain an understanding of their operating environments using a variety of means, including activities initiated by the regulator and participation in forums organised by stakeholders.</p> <p>In 2015-16, NICNAS convened public meetings and meetings with interested stakeholders on a range of matters that provided opportunities for the regulated sector to provide feedback to NICNAS, including:</p> <ul style="list-style-type: none"> <li>• Quarterly meetings with our main stakeholder advisory group, the NICNAS SCC (comprised of industry and community representatives). The SCC was established in 2015-16 to provide strategic advice to the Director of NICNAS on the operation of scheme.</li> <li>• The NICNAS reforms - public consultation on 3 consultation papers, 6 stakeholder workshops with over 300 attendees, bilateral consultation with over 100 organisations.</li> <li>• Outcomes of chemical assessments – in the case of new chemicals, NICNAS engages with the notifier of the chemical under assessment. For existing chemicals (eg. (IMAP) Program) NICNAS engages with a broader group of stakeholders through public consultation and targeted engagement with relevant stakeholders.</li> <li>• Stakeholder workshops on compliance with legislative requirements.</li> <li>• Targeted consultation on the review of the IMAP framework.</li> <li>• Meetings with companies and organisations involved in research and development activities (five meetings).</li> </ul> <p>NICNAS staff participated in 5 international meetings that focussed on issues such as current approaches, methodologies and challenges in chemicals assessment and regulation. These forums prove the opportunity to gain an understanding of the global chemical regulatory environment, and included industry and civil society representatives.</p> <p>NICNAS has continued to maintain active engagement with Canadian, European and US counterparts through existing cooperative arrangements that provide further opportunities to gain an understanding of common issues.</p> <p>The NICNAS stakeholder survey results indicate that industry stakeholders in frequent contact with NICNAS held</p>	<p><b>KPI 1 – Exceeded/met/not met</b></p>

2015-16 evidence	Self-assessment
<p>generally positive views about the scheme.</p> <p>There was a generally positive contact experience when requesting advice and information and over 75% of the sample who had participated in a NICNAS consultation, forum or training event in the last 12 months were either <i>satisfied</i> or <i>very satisfied</i> with the way the event was managed. The majority of stakeholders agreed that NICNAS communicated clearly with stakeholders. Key challenges remain in engaging and providing clarity and simplicity for those who are in contact with NICNAS less frequently, including those registered at lower levels. Mixed responses were received in relation to NICNAS's ability to listen to feedback (nett agree 40%; nett disagree 18%) and understand the needs of stakeholders (47%; 16%).</p>	

### 2.1.2 Measures of good regulatory performance – Actions taken to minimise the potential for unintended negative impacts of regulatory activities on regulated entities, through chemical assessments being completed within legislated timeframes

2015-16 evidence	Self-assessment
<p>Industry feedback has confirmed that time to market for new chemicals has a significant impact on businesses. The scheme has legislative provisions for low risk (to human health and/or the environment) chemicals that enable introduction of these chemicals without pre-market assessment by NICNAS. 11,688 new industrial chemicals were introduced by 208 introducers under exemption categories in 2015-16.</p> <p>Statutory timeframes apply to the assessment of new chemicals. NICNAS completed 311 pre-market assessments of new chemicals (208 certificates and 103 permits), 99% of which were within the legislated timeframes (exceeding the key performance indicator of 96% set in the Portfolio Budget Statement). One Priority Existing Chemical (PEC) assessment was published, also within the statutory timeframe.</p> <p>There is a statutory requirement for companies introducing chemicals that have previously been assessed by NICNAS to advise the Director if they propose to introduce the chemical under circumstances different from those assessed (secondary notifications). There were 357 secondary notification inquiries, of which 34 were further investigated because of changed circumstances and/or new data for chemicals previously assessed. Only one was found to require further assessment. Industry was informed of the outcome in these cases and was able to introduce the remaining 33 chemicals without further regulatory impost.</p> <p>Public comment was sought on 909 existing chemical assessments completed using the IMAP framework. While not a</p>	<p><b>KPI 1 – Exceeded/met/not met</b></p>

2015-16 evidence	Self-assessment
<p>legislated requirement, this approach enabled stakeholders to be informed of any risk management recommendations that could potentially result in regulatory action by state/territory regulators.</p> <p>The Chemical Gazette published monthly is the legislative mechanism to advise stakeholders of regulatory decisions. The NICNAS bulletin is a non-statutory information bulletin that includes issues of interest to all stakeholders and is published concurrently with the Chemical Gazette.</p> <p>Nine percent of the NICNAS survey sample had submitted a chemical for assessment in the last 12 months. Overall, the survey indicated that NICNAS assessments were <i>Timely</i> (nett <i>good</i> 57%; nett <i>poor</i> 15%), <i>Accurate</i> (69%; 6%), and consistent (68%; 6%). Satisfaction ratings on overall outcomes of chemical assessments showed nett satisfaction amongst the entire survey sample at just under 50% across three measures tested: <i>Processes</i> (nett satisfaction 47%; nett dissatisfaction 17%); reporting (48%; 11%); and timeliness (46%; 15%). Areas for improvement were identified as simplicity of the process and user friendliness.</p>	

### 2.1.3 Measures of good regulatory performance – Continuous improvement strategies implemented to reduce costs of compliance for regulated entities through effective contribution to international harmonisation

2015-16 evidence	Self-assessment
<p>International harmonisation of chemical regulation reduces the regulatory burden on industry and facilitates the availability of newer chemicals in Australia. In 2015-16, NICNAS maintained its active engagement with trusted international regulators through a range of fora. The OECD Chemicals Committee and its key subsidiary committees (Task Force on Hazard Assessment, Working Party on Manufactured Nanomaterials and Clearing House on New Chemicals) and activity-specific subgroups established under each of these committees were the main mechanisms through which NICNAS engaged multilaterally. Engagement with regional jurisdictions occurred through the Asia Pacific Economic Cooperation (APEC) Chemical Dialogue.</p> <p>Key outcomes from international engagement that facilitate the reduction in compliance costs for industry included:</p> <ul style="list-style-type: none"> <li>• Development of Integrated Approach to Testing &amp; Assessment (IATA) of chemicals, specifically use of defined approaches in IATA, reporting of IATA for skin sensitisation, and use of Adverse Outcome Pathways in IATA.</li> <li>• Guidance on waiving data requirements for the assessment of new chemicals in specific circumstances.</li> <li>• Use of analogues in the assessment of new chemicals.</li> <li>• Identifying future challenges relating to the safety of manufactured nanomaterials, development of approaches to nano-</li> </ul>	<p><b>KPI 1 – Exceeded/met/not met</b></p>

2015-16 evidence	Self-assessment
<p>equivalence, grouping and read-across concepts base on physical properties of nanomaterials, and alternative toxicity testing strategies for nanomaterials.</p> <ul style="list-style-type: none"> <li>• Convening a workshop on best regulatory practice and building capacity in the risk assessment of metals and metal compounds among APEC economies.</li> <li>• Evaluating risks from combined exposure to multiple chemicals.</li> <li>• Participation in the global OECD/UNEP project on perfluorinated chemicals.</li> <li>• Enhancements to the OECD QSAR Toolbox.</li> <li>• Technical input into activities of the UN Globally Harmonised System of Classification and Labelling of Chemicals.</li> <li>• Technical input to the European Commission project on commonalities and differences in approaches for testing and assessment of endocrine disruptors.</li> </ul> <p>NICNAS staff participated in 5 international meetings that focussed on issues such as current approaches, methodologies and challenges in chemicals assessment and regulation. These forums provide the opportunity to learn from and contribute to international best practice approaches.</p> <p>Ongoing engagement with our Canadian, European and US counterparts (through existing cooperative arrangements) facilitated access to scientific expertise, assessment tools and methodologies, enabling Australia's industrial chemicals regulation to remain at world's best practice. Engagement occurs predominantly through electronic means and tele/video conferencing (7 tele/video conferences in 2015-16) and in the margins of various multilateral meetings.</p> <p>The ICNA Act includes provisions for lower fee options for new chemicals assessed under comparable agency or approved foreign scheme provisions. These assessment categories are established as a direct outcome of active bilateral engagement and trust established through many years of working closely with international counterparts.</p> <p>In 2015-16, seven comparable agency assessments were received (three Canadian reports, four US reports) and eleven foreign scheme assessments were received as input to new Chemicals assessments.</p> <p>The NICNAS SCC was provided with quarterly performance reports that detail NICNAS's international engagement and the outcomes of such engagement.</p>	

## 2.2 KPI 2 – Communication with regulated entities is clear, targeted and effective

### 2.2.1 Measure of good regulatory performance – Guidance material is kept up to date and complies with government accessibility guidelines

Performance output/evidence	Self-assessment
<p>NICNAS launched a new search engine in September 2015 for the NICNAS website to improve navigation of website content, including chemicals listed on the Australian Inventory of Chemical Substances (AICS) and assessment reports. Additional metadata continues to be added to all website content, to further improve search results.</p> <p>The website includes a range of guidance materials including the NICNAS Handbook for Notifiers, information on how to register your business, cosmetics and soaps, information for chemical assessments, various FAQs, fact sheets and information on industry obligations.</p> <p>NICNAS developed and launched six online decision tools on the website to assist stakeholders understand the risk matrices for categorisation of new chemicals under the NICNAS reforms, whether they need to register their business with NICNAS and to determine if a chemical is a cosmetic.</p> <p>NICNAS has initiated a redevelopment of its website with a focus on compliance with the Digital Transformation Office's Digital Service Standard. NICNAS has commenced systematically updating website content and has currently converted 47% (1,175 of 2,500) of documents on the NICNAS website to an accessible format, to comply with the Australian Government WCAG 2.0 accessibility guidelines. To further ensure user satisfaction, NICNAS is planning to institute a Webpage feedback form and to survey website users in order to measure user satisfaction.</p> <p>The NICNAS stakeholder survey indicated over one third (36%) of stakeholders had visited the NICNAS website in the last 12 months. Ratings across a range of measures were generally good. <i>Accuracy</i> (nett <i>good</i> 69%; nett <i>poor</i> 3%), <i>Quality and readability of content</i> (62%; 10%) and <i>Accessibility</i> (58%; 8%) rated strongly. Of those 36% described above, over half indicated that the website met their needs and nett satisfaction with the website was at 58% amongst the entire survey sample. Areas for improvement included navigation, search function and ease of finding assessment reports.</p>	<p><b>KPI 2 – Exceeded/met/not met</b></p>

## 2.2.2 Measures of good regulatory performance – Targeted stakeholder consultation and engagement with regulated entities, to provide feedback as appropriate

Performance output/evidence	Self-assessment
<p>Stakeholder consultation and engagement can be either public engagement (eg consultation of documents published on the NICNAS website, public meetings etc.) or targeted engagement with those stakeholders impacted by a particular issue.</p> <p>In 2015-16 <u>public comment</u> was sought on the following:</p> <ul style="list-style-type: none"> <li>• <b>NICNAS Reforms</b> – publication of 3 consultation papers, six public workshops attended by over 300 participants.</li> <li>• <b>IMAP assessments</b> – NICNAS published 4 tranches (Tranche 15, 16, 17 and 18) of IMAP assessment reports (909 human health and/or environmental chemical assessments) for public comment.</li> <li>• <b>Secondary notifications</b> (reassessment of previously assessed chemicals) - publication of reports for four chemicals previously assessed as new chemicals for public comment.</li> <li>• <b>PEC</b> – public consultation prior to finalising the report.</li> <li>• <b>Amendments to chemicals on AICS</b> - proposed inclusion of particulars (conditions of use) for four chemicals.</li> </ul> <p><u>Targeted consultation</u> was undertaken for:</p> <ul style="list-style-type: none"> <li>• <b>NICNAS Reforms</b> –Ministerial round table discussion with key industry stakeholders to discuss the NICNAS Reforms and launch the implementation plan for the reforms.</li> <li>• <b>IMAP</b> –NICNAS engaged with local and international industry bodies/associations to inform and obtain information and feedback on IMAP assessments.</li> <li>• <b>IMAP Review</b> –NICNAS sought feedback from national and international industry bodies/associations on application of the IMAP framework. Due to the large volume of assessment published for public comment per tranche, Industry was of the view that the pace should be balance with Industry’s ability to effectively review assessment outputs. NICNAS is currently considering how to use the feedback obtained from the IMAP Review for IMAP Stage 2.</li> <li>• <b>New chemicals assessment reports</b> –201 new chemical notifiers were provided the opportunity to comment on assessment reports.</li> <li>• <b>NICNAS Stakeholder survey</b> – feedback was sought on a range of service areas including: <ul style="list-style-type: none"> <li>• Understanding and comprehension of requirements, scope and coverage of the scheme;</li> <li>• Guidance and advice;</li> </ul> </li> </ul>	<p><b>KPI 2 – Exceeded/met/not met</b></p>

Performance output/evidence	Self-assessment
<ul style="list-style-type: none"> <li>• Registration processes;</li> <li>• Australian Inventory of Chemical Substances;</li> <li>• Communications, information and advice;</li> <li>• Stakeholder interactions and engagement;</li> <li>• Communications and information;</li> <li>• NICNAS website:</li> <li>• Chemical assessments;</li> <li>• NICNAS events; and</li> <li>• Overall satisfaction.</li> </ul>	

### 2.2.3 Measures of good regulatory performance – Regulatory decisions and advice are provided in a timely manner, are consistent and support predictable outcomes

Performance output/evidence	Self-assessment
<p>In 2015-16:</p> <ul style="list-style-type: none"> <li>• 99% regulatory decisions relating to new chemical assessments were made within legislated timeframes (key performance indicator 96%).</li> <li>• PEC report – one PEC report was published.</li> <li>• Secondary notifications (reassessment of previously assessed chemicals) – four secondary notification assessments were completed and published in 2015-16.</li> <li>• Timely advice to risk managers: the Delegate for the Poisons Standard and SafeWork Australia.</li> <li>• 100% of registration decisions were processed within legislated timeframe of 30 days – over 6000 registrants.</li> <li>• AICS listing of chemicals - 203 chemicals were listed on the AICS including 18 corrected or updated and 3 deleted due to misidentification.</li> <li>• Processing confidential listing applications – nine applications were processed and approved, one was withdrawn and none were rejected.</li> <li>• No NICNAS decisions were referred to the AAT for review.</li> </ul> <p>The NICNAS stakeholder survey reported guidance and advice provided by NICNAS as generally strong.</p>	<p><b>KPI 2 – Exceeded/met/not met</b></p>

Performance output/evidence	Self-assessment
<ul style="list-style-type: none"> <li>Registration of businesses - NICNAS provides <i>Clear guidance on company registration obligations</i> (66% agree) and <i>Clear guidance to assist me to register</i> (61% agree) with strong nett <i>good</i> ratings of 59% - 64% across measures of <i>Timeliness</i>, <i>Simplicity</i> and <i>Clarity</i>. Areas for future focus include <i>Reasons for decisions</i> (38% nett agreement; 18% nett disagreement) and <i>Reasons for processes</i> (41%; 20%).</li> <li>Operation of the AICS - strong outcomes on <i>Accuracy</i> (nett <i>good</i> 70%; nett <i>poor</i> 8%) and <i>Simplicity</i> (64%; 10%).</li> <li>Provision of advice - experiences were generally positive across measures of <i>Timeliness</i> (nett <i>good</i> 71%; nett <i>poor</i> 6%), <i>Ease of contact</i> (75%; 7%), <i>Customer focus</i> (66%; 13%), <i>Clarity</i> (69%; 10%) and <i>Accuracy</i> (72%; 4%).</li> </ul>	

#### 2.2.4 Measures of good regulatory performance – Industry understands reasons for information requests

Performance output/evidence	Self-assessment
<p>Requests by NICNAS for information from introducers of new chemicals are based on legislative requirements and requests include the rationale for the request. Information requests include contact details for staff if further information or clarification is required.</p> <p>In the case of existing chemicals, voluntary approaches are used before mandatory calls for information are made (only in circumstances specified in legislation).</p> <p>The NICNAS Stakeholder Survey sought responses in relation to specific areas. Key core business areas of registration requirements and feedback on new chemical applications showed the strongest outcomes. Key opportunities for improvement were identified in relation to communicating the reasons for fees and charges, new and emerging issues and new chemical application requirements. Where comparable results were available from previous surveys, there was a trend towards improvements across communications, information and advice outcomes. Stakeholder in more frequent contact with NICNAS tended to rate the outcomes more favourably across the range of measures, information and advice.</p>	<p><b>KPI 2 – Exceeded/met/not met</b></p>

## 2.3 KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed

### 2.3.1 Measures of good regulatory performance – Assessment effort is proportionate to the risk of the chemical

Performance output/evidence	Self-assessment
<p><b>Existing chemicals:</b> In 2015-16, NICNAS applied the science and risk-based IMAP framework to the assessment of chemicals on the AICS. This framework is designed to match the assessment effort with the risk of chemicals to human health and the environment. It consists of three tiers of assessment, with the assessment effort increasing with each tier. Tier I assessments are high throughput assessments against agreed criteria with high level assessment information published. Tier II assessments are chemical-by-chemical evaluations against agreed criteria with assessment reports published. Tier III assessments are in-depth chemical-by-chemical assessments with detail assessment reports published.</p> <p>Over a four year program (Stage 1 of IMAP), NICNAS had completed 5114 human health and environment assessments for 3419 unique industrial chemicals (2372 Tier I, 2731 Tier II and 11 Tier III assessments). This total included 909 assessments completed in 2015-16 (583 Tier I, 315 Tier II and 11 Tier III).</p> <p><b>IMAP Review:</b> On 30 June 2016, NICNAS completed Stage One of the application of the IMAP framework. The completion of Stage One included a review of the framework to see if it had achieved its original purpose and to identify any areas for improvement. The application of the IMAP framework was found to have 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. A number of opportunities were identified to improve the prioritisation and assessment process for industrial chemicals listed on the AICS. These improved processes should contribute to a more robust and efficient framework that can be applied to the large number of unassessed chemicals (approximately 34,000) remaining on the AICS.</p> <p><b>PECs and secondary notifications</b> – Chemicals are declared as priority existing chemicals (PECs) based on health and/or environmental concerns. Secondary notifications are undertaken in situations where changed circumstances of use may result in higher or changed risk from that originally assessed by NICNAS. The ICNA Act specifies detailed requirements for the declaration and assessment of a priority existing chemical or secondary notification. These legislative requirements are highly prescriptive and inflexible and limit NICNAS’s ability to vary assessment steps and timeframes. The proposed approach to implementing reforms to NICNAS will address these issues.</p> <p><b>New chemicals:</b> The current new chemicals assessment framework does not adequately take into account the potential risk of a new chemical in the level of assessment required. The assessment categories are primarily dependent on introduction volumes, and the risk posed by these chemicals determines the regulatory effort only to a limited extent. Matter to be</p>	<p><b>KPI 3 – Exceeded/met/not met</b></p>

Performance output/evidence	Self-assessment
<p>considered and statutory timeframes for various categories of new chemicals assessments are specified in the legislation, which limits NICNAS's ability to vary assessment steps and timeframes. The proposed approach to implementing reforms to NICNAS will address these issues.</p> <p>NICNAS's assessment approach for new and existing chemicals is extensively documented on the NICNAS website through the Handbook for Notifiers and IMAP guidance documents.</p> <p>The NICNAS Stakeholder Survey sought responses in relation to the communication of the <i>Implementation of changes and reforms</i>, where 46% of respondents felt the communications and information was good or very good, 36% average and 19% felt the outcomes were poor.</p>	

### 2.3.2 Measures of good regulatory performance – Compliance and enforcement actions are proportional to risk and regularly reassessed

Performance output/evidence	Self-assessment
<p>Our approach to compliance is clearly articulated on the NICNAS website and is similar to the model used by other Commonwealth regulators. Compliance is achieved primarily through education and awareness-raising activities, underpinned by regular compliance monitoring. Formal compliance action was initiated in the small number of cases where efforts to achieve voluntary compliance were unsuccessful or inappropriate.</p> <p>During 2015-16, all known or potential instances of non-compliance were prioritised and actioned based on risk assessment of the likelihood and level of harm resulting from the non-compliance. Additionally, compliance monitoring activities around the new chemical obligations of the ICNA Act have been designed to incorporate a number of levels of risk assessment to ensure those companies assessed as being of greater risk of non-compliance are targeted first. During 2015-16, a target group of 55 introducers were required to provide information to NICNAS following the risk assessment of a starting group of 588 high level introducers.</p> <p>The NICNAS SCC Terms of Reference include the provision of strategic advice on mechanism to more efficiently and effectively achieve the objects of the ICNA Act, which include advice on NICNAS's compliance monitoring and enforcement activities. The SCC is provided quarterly reports on compliance related activities.</p>	<p><b>KPI 3 – Exceeded/met/not met</b></p>

## 2.4 KPI 4 – Compliance and monitoring approaches are streamlined and coordinated

### 2.4.1 Measures of good regulatory performance – Regulated entities' feedback obtained on compliance approach

Performance output/evidence	Self-assessment
<p>In 2015-16, NICNAS consulted with its Strategic Consultative Committee, peak industry bodies and individual companies prior to proposed compliance activity. The ongoing assessment of level C and D registrants for compliance with the new chemical obligations of the ICNA Act was the subject of previous consultation.</p> <p>Stakeholder survey results indicate that regulated entities believe that NICNAS provides clear guidance and information on general compliance requirements (nett agree 51%), registration obligations (66%), and new chemicals obligations (49%). The survey also indicated that NICNAS communications and information on <i>Compliance requirement for business</i> was good or very good with 19% of respondents indicating that the outcomes were nett poor.</p>	<p><b>KPI 4 – Exceeded/met/not met</b></p>

### 2.4.2 Measures of good regulatory performance – Coordinated programs and shared information with other regulatory agencies

Performance output/evidence	Self-assessment
<p>NICNAS continued to share information with other regulatory agencies and provide advise into coordinated programs such as:</p> <ul style="list-style-type: none"> <li>• Sharing of information with Australian Border Force regarding suspected false declaration as an outcome of investigation into potential non-compliance with the ICNA Act.</li> <li>• Sharing of information with other regulators on potential and known issues of compliance relating to cosmetic products via the Cosmetic Interface Working Group (NICNAS/TGA/ACCC).</li> <li>• Provision of advice to the Designated National Authority (Department of the Environment and Energy) on the regulatory status of chemicals subject to the Prior Informed Consent procedure under the Rotterdam Convention (16).</li> </ul>	<p><b>KPI 4 – Exceeded/met/not met</b></p>

### 2.4.3 Measures of good regulatory performance – Requests for information from industry are made only when necessary. Information shared internally where appropriate.

Performance output/evidence	Self-assessment
<p>NICNAS requests for information are made only when information is not readily available from other sources. NICNAS utilises data provided by the Australian Border Force in a number of aspects of its compliance program, which minimises the need for businesses to provide information to NICNAS.</p> <p>This year, NICNAS used these data to identify 382 potentially unregistered introducers who were subsequently provided information regarding their registration obligations. Additionally the registration level of 546 introducers was reassessed by NICNAS without requiring any information from the registrant.</p> <p>The objects of the ICNA Act state that NICNAS is a scheme under which information about the properties and effects of chemicals are obtained from the importers and manufacturers of those chemicals. The information required from introducers of new chemicals is set out in the schedule of data requirements in the ICNA Act.</p> <p>In undertaking IMAP assessments, NICNAS only drew on a range of sources including international assessments and databases, previous NICNAS assessments, literature reviews, advice from other national and international regulators and external peer reviews. Information was obtained from Australian businesses and industry associations on a voluntary basis.</p> <p>NICNAS maintains internal databases of chemical introducers and other information, which are accessed when required to inform various compliance activities.</p>	<p><b>KPI 4 – Exceeded/met/not met</b></p>

### 2.4.4 Measures of good regulatory performance – Monitoring and inspection approaches based on risk and where possible take into account the circumstance and operational needs of the regulated entity

Performance output/evidence	Self-assessment
<p>All audit activities undertaken identified targets through application of the published <a href="#">compliance risk framework</a>.</p> <p>There were no instances where a period of less than 28 days was provided for businesses to provide requested information.</p> <p>Fifty-five organisations were approached during the year to provide information regarding their new chemicals obligations under the ICNA Act, following a risk assessment of a group of 588 high level introducers. All target organisations were provided 28 days to respond to the request and a convenient online questionnaire was developed to allow identified</p>	<p><b>KPI 4 – Exceeded/met/not met</b></p>

<b>Performance output/evidence</b>	<b>Self-assessment</b>
businesses to respond easily.	

## 2.5 KPI 5 – Regulators are open and transparent in their dealings with regulated entities

### 2.5.1 Measures of good regulatory performance – Regulatory activities are reported appropriately

Performance output/evidence	Self-assessment
<p>There are several processes through which NICNAS reports on its regulatory performance. These include:</p> <ul style="list-style-type: none"> <li>• The Portfolio Budget Statement (PBS) 2015-16 is published to inform parliament and stakeholders of the proposed allocation of resources to outcomes by entities within the Portfolio. NICNAS deliverables and key performance indicators were outlined under Outcome 7 (<a href="http://www.health.gov.au/internet/budget/publishing.nsf/Content/2015-2016_Health_PBS">Health Infrastructure, Regulation, Safety and Quality</a> - <a href="http://www.health.gov.au/internet/budget/publishing.nsf/Content/2015-2016_Health_PBS">http://www.health.gov.au/internet/budget/publishing.nsf/Content/2015-2016_Health_PBS</a>).</li> <li>• The Department of Health Annual Report includes a report on actual results against PBS key performance indicators and a report from the Director of NICNAS on the performance of the Scheme (URL to be included when published).</li> <li>• A Cost Recovery Implementation Statement (CRIS) was published in 2015-16 in accordance with the Australian Government <a href="https://www.nicnas.gov.au/about-nicnas/cost-recovery/cost-recovery-impact-statement">Cost Recovery Guidelines</a> (<a href="https://www.nicnas.gov.au/about-nicnas/cost-recovery/cost-recovery-impact-statement">https://www.nicnas.gov.au/about-nicnas/cost-recovery/cost-recovery-impact-statement</a>). The CRIS outlines the NICNAS charging structure for 2015-16, which were established in consultation with stakeholders.</li> <li>• This Regulator Performance Framework self-assessment report is prepared in accordance with the Government-agreed framework. The framework establishes a common set of performance measures that allows for the assessment of regulator performance and their engagement with stakeholders.</li> <li>• Monthly publication of the Chemical Gazette (12 editions published in 2015-16) as required under the ICNA Act.</li> <li>• Monthly publication of the NICNAS Bulletin (12 editions published in 2015-16) non-statutory notices relevant to the administration of the scheme.</li> </ul> <p>The above documents are all published on or linked through the NICNAS website.</p>	<p><b>KPI 5 – Exceeded/met/not met</b></p>

### 2.5.2 Measures of good regulatory performance – Industry workshops and training activities conducted

Performance output/evidence	Self-assessment
<p>In 2015-16, NICNAS conducted the following industry workshops and training activities:</p> <ul style="list-style-type: none"> <li>• Workshops on general regulatory obligations - thirteen information sessions with 616 registrants.</li> <li>• NICNAS reforms - six consultation workshops and 2 technical workshops held in Sydney and Melbourne with over</li> </ul>	<p><b>KPI 5 – Exceeded/met/not met</b></p>

Performance output/evidence	Self-assessment
<p>300 attendees.</p> <ul style="list-style-type: none"> <li>One outreach session on regulatory requirements for industrial nanomaterials to the university research sector.</li> </ul> <p>The NICNAS stakeholder survey reported high levels of satisfaction with industry workshops and training events. Seventeen percent of the survey sample had participated in a NICNAS consultation, forum or training event in the last 12 months. Satisfaction with the events attended was high (76% - <i>Satisfied</i> (40%) or <i>Very satisfied</i> (36%)) with only 4% recording any level of dissatisfaction.</p>	

### 2.5.3 Measures of good regulatory performance – Open and responsive to requests from regulated entities regarding the operation of the regulatory framework

Performance output/evidence	Self-assessment
<p>The NICNAS <a href="#">Service Charter</a> sets out service standards that stakeholders can expect from NICNAS staff and how complaints will be handled (<a href="https://www.nicnas.gov.au/about-nicnas/our-service-charter">https://www.nicnas.gov.au/about-nicnas/our-service-charter</a>). Formal (NICNAS stakeholder survey) and informal feedback from our stakeholders provide regular and ongoing feedback on the manner in which NICNAS responds to requests from regulated entities.</p> <p>In 2015-16 NICNAS received one formal complaint that was resolved in accordance with this published process.</p> <p>One in four (26%) survey respondents had contacted NICNAS for advice. Contact experiences were generally positive, with strong net good ratings and low net poor ratings across measures of <i>Timeliness</i> (net good 71%; net poor 6%), <i>Ease of contact</i> (75%; 7%), <i>Customer focus</i> (66%; 13%), <i>Clarity of advice</i> (69%; 10%) and <i>Accuracy of advice</i> (72%; 4%).</p> <p>Around 6 in 10 respondents agreed that <i>NICNAS communicates clearly and deals with my requirements efficiently</i>. Fifty seven percent (57%) of participants agreed that <i>NICNAS consults with stakeholders</i> and 47% agreed that <i>NICNAS is open to input from stakeholders</i>, with disagreement of around 15% on both of these measures. The level of agreement that <i>NICNAS listens to feedback</i> (net agree 40%; net disagree 18%) and <i>Understands the needs of stakeholders</i> (47%; 16%) provided evidence of opportunities for improvement.</p>	<p><b>KPI 5 – Exceeded/met/not met</b></p>

#### 2.5.4 Measures of good regulatory performance – Risk based frameworks are published and available in a format that is clear, understandable and accessible

Performance output/evidence	Self-assessment
<p>The NICNAS <a href="https://www.nicnas.gov.au/regulation-and-compliance/nicnas-handbook">Handbook for Notifiers</a> published on the NICNAS website (https://www.nicnas.gov.au/regulation-and-compliance/nicnas-handbook) is a guide for introducers (importers and/or manufacturers) of industrial chemicals in Australia. It is intended to assist as an introducer in meeting NICNAS's requirements.</p> <p>While the Handbook for Notifiers is a consolidated document covering the majority of NICNAS's regulatory requirements, several other guidance documents are available on the website to assist regulated entities to comply with their obligations under the ICNA Act. Specific documents include:</p> <ul style="list-style-type: none"> <li>• <a href="#">Our compliance strategy</a>.</li> <li>• Inventory Multi-tiered Assessment and Prioritisation (<a href="#">IMAP</a>) framework.</li> </ul> <p>Where appropriate, NICNAS seeks input from key stakeholders (including through the SCC) in developing risk based frameworks.</p> <p>Overall satisfaction with NICNAS communication was positive (nett satisfaction 64%; nett dissatisfaction 11%). Measures of consultation (54%; 13%) and collaboration (49%; 14%) were less positive; however, levels of satisfaction still outweighed dissatisfaction by more than 3 to 1. Fifty eight percent of participants were satisfied with the way NICNAS provides information about chemicals.</p>	<p><b>KPI 5 – Exceeded/met/not met</b></p>

## 2.6 KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks

### 2.6.1 Measures of good regulatory performance – Cooperative and collaborative relationships with regulated entities established to improve the efficiency and effectiveness of the regulatory framework and to develop mechanisms to reduce the regulatory burden and compliance costs where appropriate to do so

Performance output/evidence	Self-assessment
<p>Business improvement processes undertaken in 2015-16 included:</p> <ul style="list-style-type: none"> <li>• Improvements to the NICNAS website including direct links to specific guidance documents such as: <ul style="list-style-type: none"> <li>• <a href="#">Our compliance strategy</a>.</li> <li>• Inventory Multi-tiered Assessment and Prioritisation (<a href="#">IMAP</a>) framework.</li> </ul> </li> <li>• Preparation for registrants to renew their registration for 2016-17 through a new online NICNAS business portal. User acceptance testing for this module was undertaken in 2015-16.</li> <li>• Instituting videoconferencing facilities to minimise travel for NICNAS staff and stakeholders, for example SCC members based interstate.</li> </ul> <p>Feedback from regulated entities on NICNAS’s consultative processes was sought through a range of means that included:</p> <ul style="list-style-type: none"> <li>• The NICNAS Strategic Consultative Committee (Four meetings in 2015-16).</li> <li>• Targeted consultation with selected stakeholders on the implementation of the IMAP framework during the Review of IMAP.</li> <li>• Changed approach to the presentation of the NICNAS reforms Consultation Papers 2 and 3 to a Q&amp;A style based on stakeholder feedback to Consultation Paper 1.</li> <li>• Technical workshops on specific topics (new chemicals risk matrices and confidential business information) to more fully engage specific stakeholder groups.</li> </ul> <p>There was generally strong agreement amongst stakeholders responding to the NICNAS survey, that the requirements applying to business (65%) and compliance responsibilities (61%) are clear. Similarly, 61% agreed that they know which chemicals are covered by NICNAS. Generally, those in more regular contact with NICNAS such as Level D registrants and Government stakeholders showed higher agreement levels (i.e. higher perceived understanding) and lower disagreement levels. Stakeholders who were in less regular contact with NICAS, such as once a year were more likely to show higher disagreement levels. It is important to recognise that many NICNAS stakeholders will have no requirement to submit a chemical for assessment or a need to understand their compliance responsibilities in the course of their dealings with</p>	<p><b>KPI 6 – Exceeded/met/not met</b></p>

Performance output/evidence	Self-assessment
<p>NICNAS. Within the subset of respondents who had submitted a chemical for assessment, <i>Complying with responsibilities regarding chemicals is clear</i> was a 70% nett agree and a 15% nett disagree. When comparing the outcomes on this question across years of the survey (2010, 2013 and 2016) nett agree has increased from 66%, 61% and 70% respectively.</p>	

## 2.6.2 Measures of good regulatory performance – Participate in regulators' forums

Performance output/evidence	Self-assessment
<p>The NICNAS Director and staff participate in (government) regulator forums such as:</p> <ul style="list-style-type: none"> <li>• Department of Health Regulators' Forum: <ul style="list-style-type: none"> <li>• Meeting of the health and agriculture portfolio regulators (one meeting in 2015-16).</li> <li>• 2015 International Best Practice Regulation Seminar.</li> </ul> </li> <li>• Community of Practice (CoP) for Commonwealth Regulators: <ul style="list-style-type: none"> <li>• The Director participated in planning group for Community of Practice, and chaired a meeting of the CoP with a focus on assessing regulatory performance.</li> </ul> </li> </ul>	<p><b>KPI 6 – Exceeded/met/not met</b></p>

### 2.6.3 Measures of good regulatory performance – Effective liaison with relevant policy agencies

Performance output/evidence	Self-assessment
<p>NICNAS works cooperatively with the Best Practice Regulation Branch within the Department’s Strategic Policy and Innovation Group, which carries policy responsibility for the ICNA Act. Administrative engagement for the purposes of the PGPA Act is with the Department’s Health Benefits Group.</p> <p>The NICNAS Reforms Steering Committee was established with membership drawn from senior officers from the Best Practice Regulation Branch, ITD and NICNAS. The Committee provides oversight to the NICNAS reforms and provides advice on the implementation detail, stakeholder management and government liaison activities. Five meetings of the NICNAS Reforms Steering Committee were held in 2015-16 before the committee was separated into policy and IT steering committees. A further two meetings of the NICNAS Reforms Policy Steering Committee and four meetings of the NICNAS Reforms IT Steering Committee were held in 2015-2016.</p> <p>NICNAS consulted with relevant Commonwealth agencies (including central agencies) on the implementation detail of the NICNAS reforms. Agencies consulted included: The Department of Prime Minister and Cabinet, Attorney-General’s Department, Department of the Environment and Energy, Department of Industry, Innovation and Science, and the Treasury. Consultation with Commonwealth agencies occurred throughout the development of the consultation papers on the NICNAS reforms and on specific issues where required.</p> <p>NICNAS provided technical input into the work of the Department’s Tobacco Control Branch in relation to chemical additives used in tobacco products and electronic cigarettes.</p>	<p><b>KPI 6 – Exceeded/met/not met</b></p>

## 2.6.4 Measures of good regulatory performance – Effective engagement with risk management agencies

Performance output/evidence	Self-assessment
<p>NICNAS continues its active engagement with Commonwealth risk managers through the following activities:</p> <ul style="list-style-type: none"> <li>• <b>SafeWork Australia:</b> (a) All chemicals assessed by NICNAS include a hazard classification according to the Globally Harmonised System of Classification and labelling of Chemicals (GHS) as an outcome of the assessment. NICNAS recommends that SafeWork Australia includes all positive classifications (and re-classifications) in the Hazardous Chemicals Information List (HCIL – formerly known as Hazardous Substances Information System (HSIS)). In 2015-16, NICNAS referred 1262 recommendations to SWA from IMAP assessments and one from secondary notification assessments. (b) NICNAS provided technical input to the SafeWork Australia review of exposure standards.</li> <li>• <b>Poisons scheduling:</b> Where a NICNAS risk assessment indicates that risk mitigation is required to ensure its safe use on public health grounds, the chemical is referred to the Poisons Scheduling Delegate (who may refer the recommendation to the Advisory Committee on Chemicals Scheduling (ACCS)) for consideration for listing on the Poisons Standard. A total of 42 existing and new chemicals were referred to the Delegate to consider chemical recommendations for the Poisons Standard during 2015-16. Advice on upcoming referrals for 24 existing chemicals was also provided.</li> <li>• <b>Consumer protection:</b> Product safety in Australia is governed by the Australian Consumer Law (ACL) administered by the Australian Competition and Consumer Commission (ACCC). No chemicals were referred to the ACCC for risk management action in 2015-16.</li> <li>• Commonwealth and State and Territory Risk Managers were consulted during the IMAP Review and assessments.</li> <li>• NICNAS provided technical input to the National Standard for Environmental Risk Management of Industrial Chemicals being developed by the Department of the Environment and Energy.</li> </ul>	<p><b>KPI 6 – Exceeded/met/not met</b></p>