Australian Government

Department of Health and Ageing

National Industrial Chemicals
Notification and Assessment Scheme

National Industrial Chemicals Notification and Assessment Scheme

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP) PILOT EVALUATION

IMAP
ACCELERATED ASSESSMENT OF INDUSTRIAL CHEMICALS IN AUSTRALIA

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Pilot evaluation of the IMAP Framework

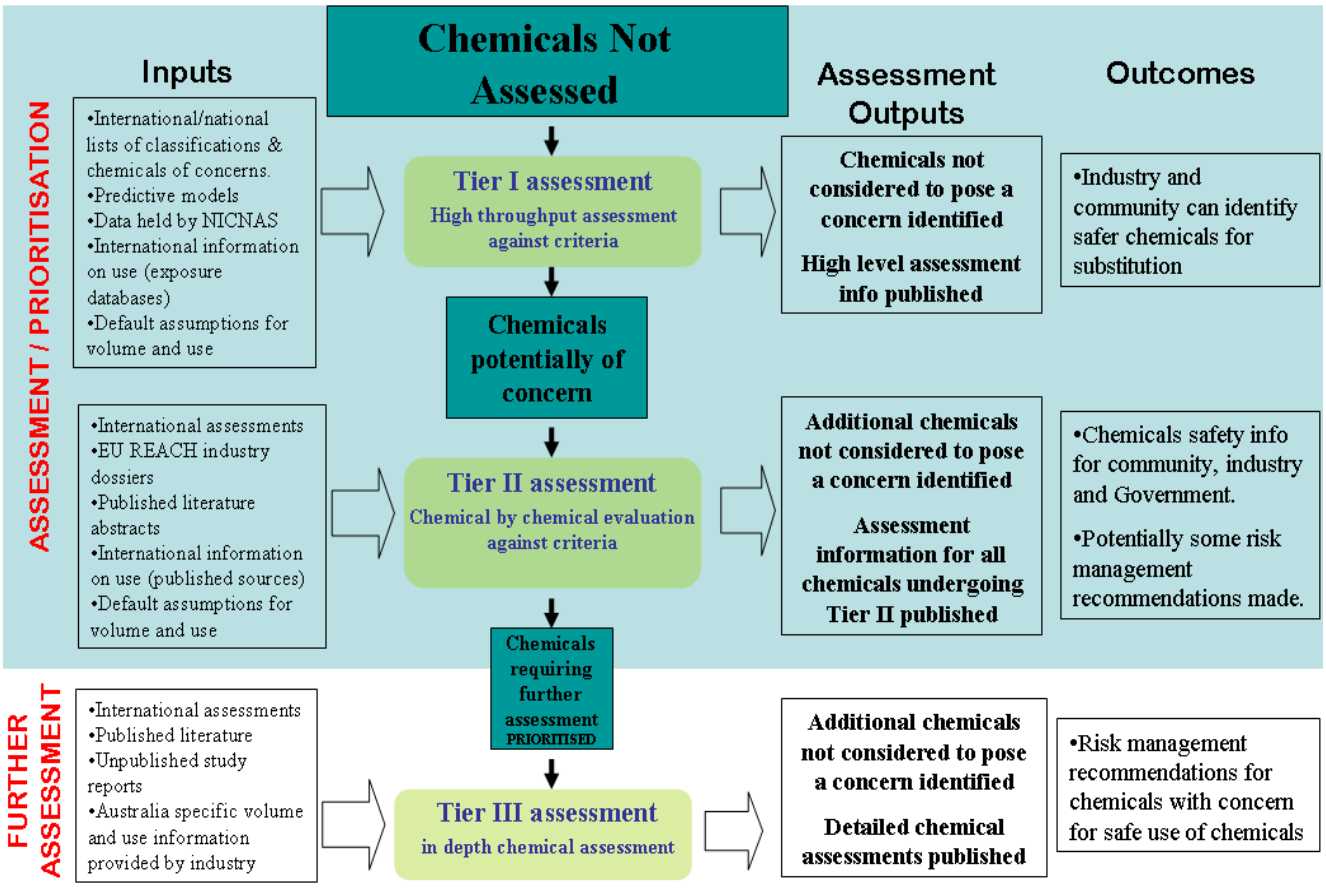
This report documents the pilot program undertaken to test the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework's viability. For further details on the framework as it is currently being implemented, please see ***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***. The framework includes: additional approaches, strategies and procedures developed during the pilot to enhance the efficiency, quality and consistency of the assessments.

Introduction

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is addressing the human health and environmental impacts of industrial chemicals, that are not yet assessed, on the Australian Inventory of Chemical Substances (AICS). NICNAS has developed an innovative framework, the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework, to accelerate this chemical assessment program. A factsheet outlining the program (***FactSheet—Overview of IMAP***) has been published on the NICNAS website (www.nicnas.gov.au).

The IMAP Framework (the Framework) is a science- and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It consists of three levels (tiers) of assessment, with the assessment effort increasing with each tier, as illustrated in Figure 1.

Figure 1: IMAP Framework



The framework uses simple and transparent criteria to determine any risks, or potential risks, to human health and the environment. Two expert working groups (EWGs) developed the scientific criteria for environmental and health hazard indicators (e.g. acute toxicity, skin sensitisation; see ***Attachment A***) and agreed which QSAR (Quantitative Structural Activity Relationship) models to use.

The stakeholder consultation and advisory groups that helped to develop the framework, the Implementation Steering Group (ISG) and Technical Working Party (TWP), agreed that a pilot should be run to evaluate the framework—including the criteria and approaches developed by the EWGs before implementation.

How the pilot was conducted

The pilot evaluation (the pilot) was conducted on 1,000 chemicals (the sample) randomly selected from AICS. The sample represented the overall distribution of chemical classes on AICS and was considered to be appropriate for the pilot.

Five key features of the framework were evaluated:

1. the scientific robustness of the risk-based approach;
2. the ability to achieve assessment outcomes early in the framework;
3. using overseas data;
4. using advancements in assessment methodologies; and
5. a flexible approach to exposure information (actual, surrogate or default).

The lessons learned from this evaluation have been incorporated into the framework, including the technical aspects.

Health hazard and environmental data from a variety of sources were tested to ascertain their usefulness for assessing chemicals at the different tiers of the framework. Data sources included:

- national and/or international classifications;
- international assessments;
- computational models; and
- empirical data.

The pilot also tested the use of surrogate exposure information from overseas sources, or conservative default values, where actual or surrogate Australian information is not available.

As a consequence, several approaches and strategies were developed to efficiently assess the chemicals through Tiers I and II of the framework.

Tier I assessment

The Tier I assessment has both an assessment and prioritisation role. The primary aim of a Tier I assessment is to identify those chemicals that are not expected to pose a concern to workers, public health or the environment so that further resources are not unnecessarily spent on the assessment. These chemicals are considered fully assessed at the end of Tier I.

The balance of chemicals is then prioritised for further assessment at Tier II.

This is a high throughput approach using tabulated electronic data that are either:

- publicly available;
- held by NICNAS; or
- readily generated using QSAR modelling.

These data can be efficiently applied to all chemicals on AICS to assess:

- health effects;
- environmental effects; and
- exposure indicator criteria.

Human health and environmental assessments use different tools and approaches. Assessing risks to humans, including workers and the general public, uses a single set of tools and approaches. A document on the framework which further describes these tools and approaches (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

Tier I human health and environment assessments were conducted on over 80% of the sample including the major chemical classes:

- organics;
- polymers;
- inorganics; and
- organic metal salts.

Approaches were developed and tested for the remaining chemical classes: unknown or variable compositions, complex reaction products and biological materials (UVCBs), and organometallic compounds.

Chemicals of inherently low concern to human health and the environment, were identified by applying expertly validated rules (see ***Key feature 2: Development of Tier I exclusion filters***).

QSAR modelling was conducted on all appropriate chemicals (i.e. approximately 700) for both human health and the environment. The QSAR models used were approved by the Human Health and Environmental EWGs (HHEWG and EEWG).

To identify human health hazards, the Organisation for Economic Cooperation and Development (OECD) QSAR Toolbox[1], OASIS's TIMES models[2] and TOPKAT[3] were used. Environment hazard identification used OASIS's POPs[4] and CATALOGIC[5], and the United States Environment Protection Agency Estimation Programs Interface (EPI) Suite[6] (including the BIOWIN and ECOSAR modules).

[1] OECD QSAR Toolbox v 2.0 <http://www.oecd.org/chemicalsafety/assessmentofchemicals/theoecdqsartoolbox.htm>
[2] OASIS's TIMES MIX V.2.26.5 Laboratory of Mathematical Chemistry. Bourgas, Bulgaria, <http://oasis-lmc.org>
[3] DS TOPKAT v2.5 Accelrys <http://accelrys.com/solutions/scientific-need/predictive-toxicology.html>
[4] OASIS's POPs v2.58.7. Laboratory of Mathematical Chemistry. Bourgas, Bulgaria, <http://oasis-lmc.org/?section=software&swid=2>
[5] OASIS CATALOGIC v5.10.9. Laboratory of Mathematical Chemistry. Bourgas, Bulgaria, <http://oasis-lmc.org/?section=software&swid=1>
[6] US EPA (2011) Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington DC, USA, <http://www.epa.gov/oppt/exposure/pubs/episuite.htm>

One of the key tools developed to characterise the human health risk at Tier I of the framework is a matrix. This is used to group chemicals with similar level of concern, based on their potential human health hazard and the potential for exposure, for further assessment. The matrix is used to characterise risks for both workers and the public.

The matrix has five hazard bands representing different severities of hazard indicators, and five exposure bands, which represent a different relative potential for exposure. There is an increase in the hazard indicator severity when moving from hazard band zero (no indication of hazard) to hazard band four. Similarly, the highest and lowest potential for exposure are bands four and zero respectively. Zero equals a chemical that does not meet the definition of an industrial chemical as defined in the *Industrial Chemicals (Notification and Assessment) Act 1989*, or is known not to be introduced into Australia.

Figure 2: Tier I human health assessment and prioritisation matrix

Increasing exposure

Increasing hazard

		Exposure band				
		0 (no exposure)	**1**	**2**	**3**	**4**
Hazard band	**0 (no indication of hazard)**	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*
	1	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*	Requiring further assessment**
	2	Not expected to pose a concern*	Not expected to pose a concern*	Not expected to pose a concern*	Requiring further assessment**	Requiring further assessment**
	3	Not expected to pose a concern*	Not expected to pose a concern*	Requiring further assessment**	Requiring further assessment**	Requiring further assessment**
	4	Not expected to pose a concern*	Requiring further assessment**	Requiring further assessment**	Requiring further assessment**	Requiring further assessment**

*Tier I assessment complete **Tier II assessment required

The approved hazard indicators (e.g. acute toxicity, skin sensitisation; see ***Attachment A***) and order of severity dictated the indicator hierarchy. Hazard bands were developed from this, based on the level of risk of each hazard indicator under the exposure conditions relating to the use category:

cosmetic, domestic, commercial and site-limited. The hazard bands have subsequently been subjected to independent validation.

The exposure bands were finalised at a multi-stakeholder workshop held in March 2012 (see ***Key feature 5***).

On the basis of the available information, a chemical will be determined as either 'not expected to pose a concern' or 'requiring further assessment' depending on the highest exposure and hazard bands assigned. Although exposure to public and workers are considered separately, the highest exposure band from each of these considerations is used for risk characterisation for any given chemical.

A document on the framework which further describes the matrix and the hazard and exposure bands (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

Tier II assessment

The aim is to:

- refine assumptions from the Tier I assessment to identify more chemicals that pose no unreasonable risk to human health or the environment;
- identify those chemicals that require further assessment to determine their risk and recommend regulatory controls for safe use;
- provide high level hazard and/or risk information for chemicals; and
- make recommendations on regulatory controls for the safe use of chemicals.

The Tier II assessment is an evaluation of risk information on a substance-by-substance or chemical category-by-category basis[7]. The Tier II hazard and risk information (combined with any information from Tier I) is summarised in a Tier II assessment template developed in consultation with stakeholders. Where appropriate, recommendations on regulatory controls for safe use and/or further assessment at Tier III will be made.

The number of Tier II assessments undertaken was based on the resources available, then evaluated to see whether or not further assessments were required to draw valid conclusions. In total, 126 human health and 23 environment Tier II assessments were completed.

Some aspects of the Tier I assessment could not be completed within the expected timeframe as assessment data, such as the classification and labelling notifications (C&L) submitted by industry under the new EU Regulation on Classification, Labelling and Packaging of Substances (CLP), were not available until late in the pilot. This meant that the normal hierarchy of assessment, Tier I followed by Tier II, could not be applied. Therefore, for the pilot only, both Tier I and II assessments were undertaken in parallel. Tier II assessments were undertaken on a random selection of the sample and included chemicals that were later determined not to require a Tier II assessment.

Of the chemicals identified for Tier II assessment, 52 Tier II human health assessments were undertaken, with 32 containing sufficient information to formulate proposed recommendations at this

[7] A chemical category is a group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity.

level (see ***Key feature 1***), without the need to identify suitable analogue chemicals (chemicals with a similar characteristics) to fill gaps in the available data. More information on the outcomes of the Tier II assessments is provided in Figure 3.

The experience gained from the Tier II assessment process helped to shape the Tier II assessment methodology, template and internal guidance documents.

Outcomes of the pilot: Key findings and lessons learned

Key feature 1: scientifically robust risk-based approach

Assessing different chemical classes

Methods have been developed and tested for assessing different classes of chemicals at Tier I. NICNAS successfully tested methods for polymers, organic metal salts, organic and inorganic chemicals, with testing also completed for UVCB and organometallic chemicals on a small subset. A document about the framework, which further describes these methods (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***), has been published on the NICNAS website (www.nicnas.gov.au).

Human health criteria and risk characterisation

The relevant hazard indicators agreed by the HHEWG (acute toxicity, corrosivity/irritation, sensitisation, repeat-dose toxicity, genotoxicity, carcinogenicity, reproductive/developmental toxicity, neurotoxicity and endocrine disruption) could be identified using Tier I data sources. Data availability for neurotoxicity and endocrine disruption was extremely limited, but international lists of endocrine-disrupting and neurotoxic chemicals were identified for use in Tier I.

The pilot demonstrated that the matrix used for human health risk characterisation in Tier I was a time-efficient tool for identifying chemicals that are not expected to pose a concern to workers and public health (assessment), and identifying those that required further assessment at Tier II (prioritisation).

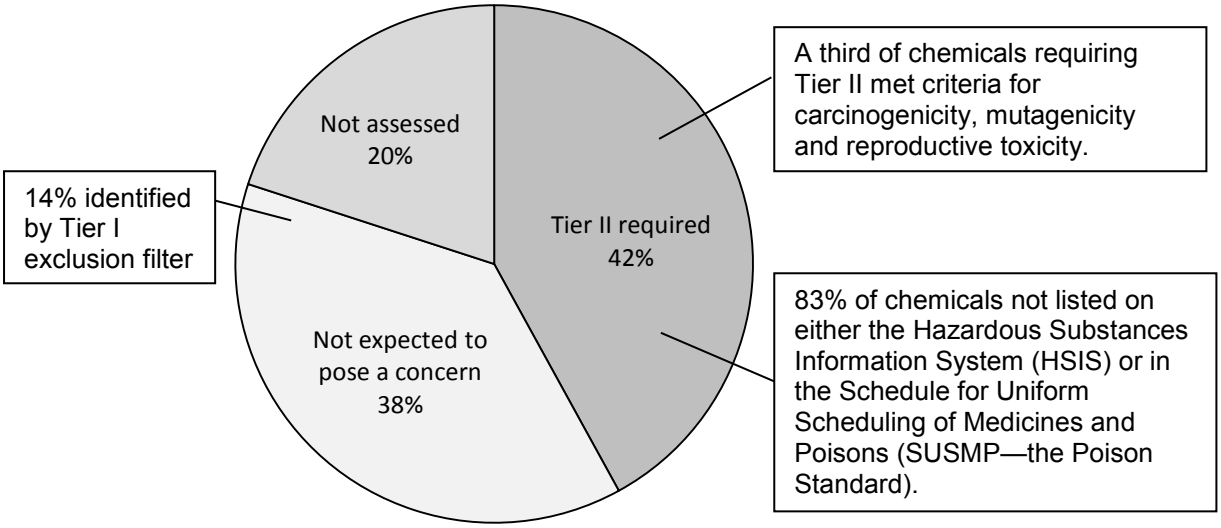
The Tier I assessment showed that 42% of the chemicals required a Tier II assessment for human health (worker and public health). A third of those chemicals met criteria for carcinogenicity, mutagenicity and reproductive (CMR) toxicity, while 83% (of the 42%) were not listed on either the Hazardous Substances Information System (HSIS) or in the Schedule for Uniform Scheduling of Medicines and Poisons (SUSMP—the Poison Standard). This analysis of existing regulatory controls at Tier I indicated that a number of chemicals identified for Tier II assessment may require additional regulatory controls. The outcomes of the human health Tier I assessment are illustrated in Figure 3.

Risk-based recommendations for regulatory controls and/or further assessment were made for a majority of the 32 chemicals for which there was sufficient information to formulate recommendations. This is consistent with the analysis of existing regulatory controls at Tier I (83% above) and demonstrates the appropriateness of the Tier I matrix as a prioritisation tool (see ***Key feature 2*** for more information).

An analysis of the Tier II assessments conducted, as a validation process, on those chemicals that were found not to pose a concern based on the Tier I data, supported the appropriateness of the matrix as an assessment tool to deliver Tier I assessment outcomes. This process helped to develop

the Tier I validation step (described below), discovered some additional sources to identify hazardous chemicals in Tier I, and highlighted the need for specialist approaches for perfluorinated chemicals and azo-dyes.

Figure 3: Outcomes of human health Tier I assessment in the pilot



Environmental criteria and risk characterisation

The approach to environmental risk assessment in the framework is based on the standard risk-assessment paradigm for chemicals—the internationally-accepted four-step hazard identification, dose-response assessment, exposure assessment and risk characterisation. This involves comparing the predicted concentrations of chemicals in the environment with the no-effect concentration for each individual substance. A potentially unreasonable risk to the environment is indicated where the predicted environmental concentration exceeds the no-effect concentration.

The framework builds on the standard risk-assessment paradigm by including additional measures designed to identify substances of inherently high concern, based on specific combinations of environmental hazard characteristics endorsed by the EEWG. The key hazard characteristics are the environmental persistence (P), bioaccumulation potential in organisms (B), and (eco)toxicity (T) of a chemical. Chemicals which exceed the nationally adopted thresholds for all three of these environmental hazard characteristics are categorised as PBT chemicals. These are considered to be of inherently high concern for the environment and are prioritised for environmental assessment in the framework.

More than 80% of the sample had their environmental risk assessed using high throughput methods, validating this approach. Of these, using conservative default assumptions at Tier I, 27% were identified as being of low environmental concern. Subsequent developments in the assessment methodology included enhanced computer modelling to identify additional chemicals of low environmental concern at Tier I, reducing the need for a more in-depth assessment at Tier II.

The assessment methodology developed in the pilot was also able to quantify the key environmental hazard characteristics of chemicals as recommended by the EEWG.

The lessons learned from the pilot resulted in significant refinements to the environmental risk assessment methodology to be used in the framework. These include developing a comprehensive pre-assessment profiling system to identify a greater range of international environmental hazard warning flags, and new sources of high quality hazard data for existing chemicals.

Ensuring quality and consistency of assessments

During the pilot, a Tier I validation step was developed to strengthen the framework's scientific rigour. This step includes a:

- preliminary review of information on a particular aspect of the assessment, e.g. exposure or verification of a QSAR result, where it could change the outcome of the Tier I assessment;
- cross check of chemicals not expected to pose a concern against national/international lists of 'concern' chemicals; and
- peer review of chemicals not expected to pose a concern by an acknowledged expert.

Experience gained from the pilot informed the development of a number of other mechanisms to ensure quality and consistency in the assessment and prioritisation process including:

- strengthened assessment methodologies;
- scientific guidance material for assessors;
- standard operating procedures;
- a peer review strategy; and
- a staff training program.

The pilot also highlighted the need to use standardised automated reporting tools to produce consistent environmental and human health assessment reports and increase efficiency.

These tools have been built into the Electronic Information Management System (EIMS), established since the pilot's completion. The EIMS will efficiently manage, organise and track the large amounts of input and output data generated through IMAP, and help in project management, assessment and reports, and progress reporting.

Key feature 2: Achieving assessment outcomes early in the framework

Lessons learned from the Canadian experience of categorising their chemical inventory (the Canadian Domestic Substances List—DSL) and advice from stakeholders, including industry and community, ensured that early assessment outcomes were incorporated into the framework. A factsheet outlining the assessment outcomes at each tier (***FactSheet 3—Better chemical safety***) has been published on the NICNAS website (www.nicnas.gov.au). The pilot demonstrated that early assessment outcomes can be produced at Tier I and Tier II.

Development of Tier I exclusion filters

To increase efficiency, the ISG and TWP agreed that certain chemicals of inherently low concern to human health and the environment (e.g. polymers of low concern) should be identified as a first step in the framework.

Tier I exclusion criteria were developed to identify:

- polymers with reactive functional groups consistent with polymers of low concern (PLCs);
- chemicals of low concern; and
- chemicals on AICS with a high probability of not having an industrial or cosmetic use (i.e. excluded use chemicals having therapeutic or pesticide use, which are assessed by the Therapeutic Goods Administration—TGA, and the Australian Pesticides and Veterinary Medicines Authority—APVMA, respectively).

Subsequently, 144 chemicals (i.e. 14% of chemicals assessed) were considered not of concern based on meeting the Tier I exclusion criteria, meaning results could have been published early in the assessment process.

A document on the framework which further describes Tier I exclusion criteria including the identification of chemicals of low concern (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

Chemical safety information

To improve chemical safety information flow to stakeholders including community, industry and risk management agencies, considerable effort was put into developing the Tier II assessment templates for both human health and the environment. The ISG was consulted when developing the key elements (the type of information useful to community, industry and risk managers) and format of the Tier II template.

Early recommendation outcomes

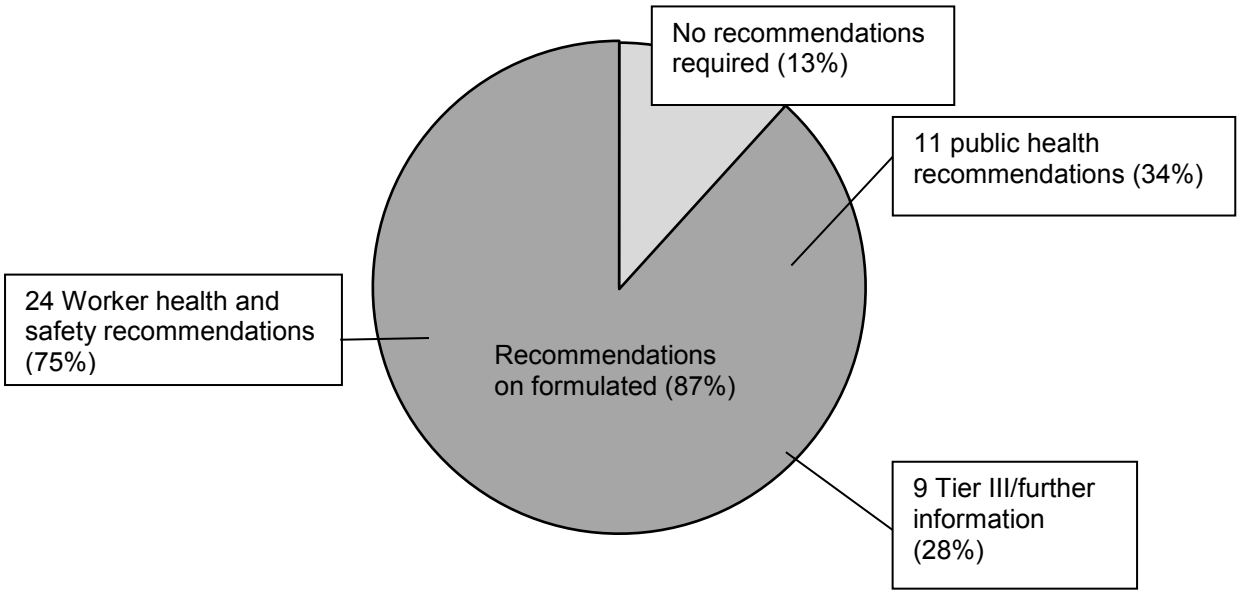
The Tier II assessment report identifies the risk to workers, the public and the environment based on information about the chemical's use; hazard and current regulatory controls and the relevance of regulatory controls applied overseas. It includes recommendations for additional regulatory controls, where necessary, to mitigate risks to workers, the public and environment as quickly as possible within the framework.

A document about the framework that further describes the information considered in the framework (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

As previously mentioned, the pilot showed that in many cases existing regulatory controls were not sufficient. Of the 32 Tier II assessments for which final proposals on the recommendations were formulated, recommendations for additional regulatory controls and/or further assessment were made for >87% of chemicals (as illustrated in Figure 3) including:

- public health recommendations for 11 chemicals (34%);
- worker health and safety (WHS) classification recommendations for 24 chemicals (75%); and
- nine chemicals (28%) recommended for further assessment at Tier III, or required more information, to determine whether further assessment is necessary (NB: there is some overlap between these three groups).

Figure 4: Outcomes of the 32 human health Tier II assessments for which recommendations were formulated



To promote early regulatory outcomes resulting from the framework assessment outputs, a workshop was held in May 2011 with Commonwealth risk management agencies to discuss the framework and the utility of Tier II assessments specifically for risk management. A number of case studies based on the pilot were discussed at the workshop. This workshop and follow-up meetings with the Advisory Committee on Chemical Scheduling (ACCS) Secretariat, Safe Work Australia and Australian Competition and Consumer Commission (ACCC) helped refine the Tier II assessment template to include key information and the data required to set safety standards.

Key feature 3: Using overseas data

Major initiatives are being undertaken worldwide to rapidly and comprehensively identify and assess existing chemicals of concern. To ensure efficiency and reduce duplication of effort, NICNAS will maximise its use of overseas information through assessing its appropriateness to the Australian context. A factsheet (***FactSheet 4—Leveraging international information***) has been published on the NICNAS website (www.nicnas.gov.au).

NICNAS has integrated international information extensively into the framework including the:

- Canadian categorisation of the DSL
- EU REACH (the regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals) and EU classification and labelling notifications
- European Commission Cosmetic Ingredient Database (CosIng)
- Scientific opinions on cosmetic substances by European Commission committees
- United States bodies such as US Environmental Protection Agency (EPA) Action Plans, US EPA's High Production Volume (HPV) program and Agency for Toxic Substances and Disease Registry (ATSDR)
- Japanese Chemicals Management Law
- New Zealand EPA
- OECD HPV Program

- OECD eChemPortal
- OECD QSAR Application Toolbox
- International Agency for Research on Cancer (IARC)
- National Toxicology Program—Report on Carcinogens (NTP RoC)
- International Programme on Chemical Safety (IPCS) publications.

This information is used to inform both the outcome of the Tier I assessment (matrix position for human health and no-effect concentration and PBT categorisation for environment) and for risk characterisation at Tier II and Tier III.

As part of the pilot, NICNAS developed a high throughput screening tool called the Hazard Flag Identification Tool (HazFIT), which automates the process of matching chemicals on AICS against hazard information from international/national classifications, empirical data and lists of concern chemicals. HazFIT is based on the Canadian experience of categorising and prioritising chemicals on the Canadian DSL. It uses information from scientifically reputable sources and is presented in a tabulated form for easy comparison.

The empirical data was extracted from a number of sources including the OECD Toolbox, eChemPortal and environmental data from the Canadian categorisation of the DSL. The data provided additional information for assessment at Tier I. The OECD eChemPortal was found to be particularly efficient for mining toxicity and ecotoxicity data from EU REACH dossiers.

HazFIT was applied to all 1000 randomly selected pilot program chemicals. This rapid assessment ability emphasised the importance of having aligned the human health criteria developed by the EWGs, with existing hazard classification frameworks already in use nationally and internationally.

However, it should be noted that the C&L notification data were found to be available only in a chemical-by-chemical search format, rendering them unsuitable for the Tier I high throughput assessment process. To assess the potential value of the C&L notification data, a chemical-by-chemical search was done for those chemicals for which no other hazard flags were identified at Tier I. From this, an additional 45 chemicals were identified for Tier II assessment, including five CMR chemicals, highlighting the usefulness of this data source. The data source was identified as a valuable source of information and will be used in the framework.

There were often multiple and varying C&L notifications from industry for an individual chemical. A strategy was developed to synthesise the multiplicity of information down to a single classification recommendation so that the information could be consistently applied at Tier I and Tier II. This involves the initial use of worst-case classification at Tier I, with the addition of a Tier I validation step if the C&L data was the sole determinant of a chemical requiring Tier II assessment. At Tier II a weight-of-evidence approach was taken to determine the appropriate classification.

The efficient and comprehensive search strategy developed during the pilot to enable rapid literature searches on chemicals assessed at Tier II, including not only commercial but publically available databases, resulted in significant resource efficiencies.

Key feature 4: Advancements in assessment methodologies

A comprehensive strategy for using QSAR models was developed and tested for both human health and environmental hazards. NICNAS and the Department of Sustainability, Environment, Water, Populations and Communities (DSEWPaC) liaised closely with the developer of the OECD QSAR Application Toolbox and OASIS's TIMES models to optimise the strategy, ensuring that it is robust, practical and resource-efficient. Further efficiencies were achieved by using the OECD QSAR Toolbox as a pre-filtering step before analysing chemicals with OASIS's TIMES models for human health hazards. This, in turn, reduced the number of intensive computer calculations needed and therefore the costs to conduct QSAR.

During the pilot it became clear that the OECD Toolbox needed to be used in the Tier II assessment process to identify suitable analogue chemicals to fill gaps in available data in order to arrive at a final conclusion on the health hazards.

The pilot process also identified a number of discrepancies in the two-dimensional (2D) structure information for each chemical (i.e. SMILES— simplified molecular input line entry system), which was critical for successful high-throughput QSAR modelling. Hence, a recognised OECD expert was engaged to check the quality of the NICNAS two dimensional (2D) structures on the 1000 pilot chemicals. Subsequently, NICNAS updated 2D structures for all the chemicals on AICS that could be represented by a specific 2D structure. Having subjected these 2D structures to quality checking, AICS now meets the criteria to be an OECD Toolbox high quality inventory.

Some computational modelling tools were identified during the pilot for improvements, which have since been implemented.

A document on the framework which further describes the use of QSAR models (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

Key feature 5: A flexible approach to using exposure information

The framework does not require industry to provide any additional chemical exposure information in the early assessment tiers (Tiers I and II). The potential for exposure (exposure band) is determined using surrogate exposure information from overseas sources, or conservative default values, where actual or surrogate information is not available.

This approach was tested in the pilot. Less than 5% of the chemicals in the pilot had actual Australian specific volume and use information (held by NICNAS through previous calls for information, e.g. high volume chemicals). A further 45% of chemicals were assigned a surrogate value for use at Tier I using high throughput exposure data sources.

To achieve this, international use descriptors from high throughput sources were assigned into broad categories with a use multiplier.

Figure 5: Exposure categories

Category	Cosmetic	Domestic	Commercial	Site-limited	Non-industrial
use multiplier	1	0.1	0.01	0.001	0

Following a workshop on IMAP exposure with independent experts in March 2012, the use category descriptors and allocation of use multipliers for the internationally-derived use codes, developed in the pilot, were refined.

About 50% of chemicals in the pilot were assigned a default volume and/or use multiplier, which meant that any chemical within hazard band 2, 3 or 4 would automatically require a Tier II assessment. As part of the Tier I validation, researchers did a chemical-by-chemical search of identified national and international sources on exposure. The result was that a number of chemicals were validated at Tier I and required no further assessment.

Further efficiencies were developed by compiling a database of the sources on exposure with a brief summary about each on the information held and its usability.

The chemical-by-chemical approach conducted as part of the Tier I validation step is resource-intensive, as there is a need to search multiple surrogate sources for a single chemical to identify the use that poses the greatest exposure risk to human health. Although it is expected that the number of chemicals for which the default volume and/or use multiplier will be lower in Stage One (see www.nicnas.gov.au) compared with the pilot, to increase efficiencies NICNAS is:

- continuing to explore possible data sources for chemical use information that are conducive to a high throughput approach. After the pilot was completed, a database on the use of Substances in Products in the Nordic Countries (SPIN) has been identified as a particularly useful source for Tier I;
- tracking the proposed extension of search capabilities for eChemPortal that will facilitate a search of REACH dossiers by 'Use' category; and
- engaging with industry to encourage them to voluntarily supply exposure information.

A document on the framework which further describes the exposure methodology, default assumptions and exposure information sources (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).

Conclusion

Based on the outcomes, the pilot was successful, confirming the appropriateness of the approaches and methodologies to be used for the framework. It also enabled additional strategies and procedures to be developed, before implementing the framework, to enhance the efficiency, quality and consistency of the assessments.

The pilot:

- confirmed the applicability of the hazard criteria and approaches developed by the EWGs;
- demonstrated the efficiency that can be gained by applying the multi-tiered framework;
- demonstrated that the framework will deliver chemical safety information and recommendations for regulatory outcomes at an early stage;
- confirmed that international information can be extensively integrated into the framework and respective assessments;
- enabled a strategy to be developed to leverage international information appropriately to ensure efficiency and reduce duplication of effort;

- validated the use of surrogate exposure information from overseas sources and conservative default exposure values where Australian data were not available;
- strengthened NICNAS's QSAR modelling capabilities and helped to develop a strategy to use this advancement in assessment methodologies;
- led to refinements in assessment tools and approaches;
- increased the framework's scientific robustness by developing internal guidance and quality assurance strategies, including a Tier I validation step and peer review strategy;
- provided information for the key elements and format required for the assessment report templates; and
- supplied the necessary features of an EIMS to ensure efficient management, organisation and tracking of the large amounts of input and output data generated through IMAP.

The enhancements to the framework identified during the pilot have been adopted for chemical assessment in Stage One of the framework's implementation.

ATTACHMENT A

Development of human health and environmental hazard criteria

Two expert working groups (EWGs) were established to develop scientific criteria for environmental and health hazard indicators respectively.

The Environmental EWG (EEWG)

Members: Dr Sneha Satya (NICNAS, Chair), Prof. Des Connell (Griffith University), Dr Suzanne Reichman (EPA VIC), Ms Therese Manning (Environment NSW), Mr David Perry (DEWHA—now DSEWPaC), and Ms Danie Dubé (Environment Canada)

The EEWG:

- defined the environmental hazard and fate indicators;
- developed scientific criteria for the indicators;
- identified QSAR models appropriate for the project;
- developed approaches for the different classes of chemicals on AICS; and
- managed the different data sources.

The members have completed this work and agreed on the criteria for the hazard indicators and the framework for determining persistence, bioaccumulation and toxicity (PBT). These criteria are based on the National PBT criteria, which have been adopted from international criteria. The guidance material for approaches for handling various classes of chemicals on AICS was made available from Canada. The members supported the use of Canadian approaches. A strategy for using QSAR models was also agreed.

The Human Health EWG (HHEWG)

Members: Dr Sneha Satya (NICNAS, Chair), Dr Les Davies (APVMA), Mr Clive Paige (QLD Health), Prof. Brian Priestly (ACHHRA—Australian Centre for Human Health Risk Assessment), Prof. Dave Winkler (CSIRO), Dr Janith Wickramaratna (NICNAS).

The HHEWG:

- identified the human health hazard indicators;
- reviewed scientific criteria developed by NICNAS for these effects; and
- advised on the practicality of using the criteria.

The HHEWG agreed on the following hazard indicators as being relevant for the project:

- acute toxicity
- corrosivity/irritation
- sensitisation
- repeat-dose toxicity
- genotoxicity
- carcinogenicity
- reproductive/developmental toxicity
- neurotoxicity
- endocrine disruption.

The group agreed on the criteria by comparing various national and international classification and labelling schemes to ensure IMAP was consistent with other countries, and ensure that their work could be used efficiently in the project.

Some health effects were regarded or weighted as more serious than others. Carcinogenicity, genotoxicity and reproduction/developmental toxicity (including neurotoxicity and endocrine disruption), were given higher weighting because they are considered more important. Therefore, the hierarchy is:

carcinogenicity = genotoxicity = reproductive/developmental toxicity = neurotoxicity =endocrine disruption > acute toxicity > repeat-dose toxicity > sensitisation > irritation.

Hazard bands derived based on this weighting developed for the pilot have since undergone a process of independent expert validation. A document on the framework which further describes the hazard bands (***Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework***) has been published on the NICNAS website (www.nicnas.gov.au).