

Review of the Existing Chemicals Program

BACKGROUND PAPER

1. Purpose of this paper

This paper describes the Existing Chemicals Program (the Program) and the national framework in which it operates, and highlights some of the current problems and future challenges. The paper provides a framework for discussions to be held with key stakeholders prior to public release of an options paper on the assessment of existing chemicals within NICNAS.

2. Introduction

The Industrial Chemicals Notification and Assessment Act 1989 (the Act) establishes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS came into effect in 1990 to regulate industrial chemicals in Australia. Previously, industrial chemicals in Australia were largely unregulated. Under the Act there are provisions for dealing with both new and existing industrial chemicals.

Existing chemicals are essentially those in use in Australia and listed in the Australian Inventory of Chemical Substances (AICS). The Program currently assesses existing chemicals on a priority basis, as there are around 40,000 chemicals on AICS.

3. National Chemical Regulatory Framework

NICNAS operates within a national chemical regulatory framework. NICNAS has overall responsibility for industrial chemicals assessment and works with Environment Australia (EA) in performing its assessment functions. NICNAS applies the National Occupational Health and Safety (NOHSC) classification, labelling and Material Safety Data Sheets (MSDS) Codes to its assessments and recommendations to facilitate a consistent national approach to safe chemical use. To avoid duplication of assessment activities, assessments are provided to other federal and state/territory agencies. The regulation of industrial chemicals beyond the point of sale is the responsibility of States and Territories, however, national frameworks such as the NOHSC Model Regulations and Codes of Practice, Dangerous Goods legislation and National Drugs and Poisons Scheduling provide consistent standards for implementation. NICNAS uses the national coordination bodies in the various sectors as the means to facilitate national uniformity when regulatory controls are recommended.

4. Why a review?

The aim is to review the efficiencies and effectiveness of the current Program with a view to positioning the Program to be more responsive to stakeholder needs.

Whilst it is clear that assessing existing industrial chemicals for health and the environment is a necessary activity within any regulatory framework, the issue of how to do this is under review. Issues such as changes to overseas existing chemicals assessment programs currently underway or already in place, in particular the processes involved in nomination, prioritisation and assessment as well the effectiveness of overseas assessment outcomes will be considered. NICNAS will be looking at how to determine national priorities for assessment, how better to utilise overseas testing and assessment program outputs and the needs of the community to have access to sound information on chemical hazards and risks.

5. The Program today

The principal, and most well known, activity of the Program is the assessment of chemicals, known as Priority Existing Chemicals (PECs), as legislated under the Act. The Program conducts a range of PEC assessments, including full risk assessments on occupational health and safety, public health and environmental effects and more focused assessments on a specific aspect of a chemical such as hazard, or use or exposure with the aim of determining whether a full risk assessment is warranted. The selection of which chemicals undergo a PEC process is based on a process that screens and ranks publicly nominated chemicals of concern.

Other activities undertaken within the Existing Chemicals Program include:

- publication of screening assessments of nominated chemicals;
- publication of chemical information collected by NICNAS following nomination of chemicals or while responding to public enquiries;
- publication of safety information sheets based upon the findings of a PEC assessment;
- collection and publication of volume and use data on industrial chemicals manufactured and or imported into Australia in high volumes; and
- contributing to international assessment programs by providing NICNAS assessments for adoption and participating in peer review of overseas assessments.

The above activities aim to provide chemical safety information for use by government agencies, industry, jurisdictions, workers and the public. Existing chemicals assessment information is made widely available through printed reports, information sheets, the web and seminars.

PEC assessments and recommendations have an important role for informing downstream control and regulation of chemicals within Australia. For instance, the assessments have contributed to safer national occupational exposure standards,

updated or new hazard classifications, removal of unacceptable risks (eg phase out of chrysotile) and revised labelling requirements (eg poisons schedule).

Another major outcome is the contribution made to international chemical assessment programs. Because of the high quality of the assessments produced by the Program, they are utilised in international forums, forming a part of Australia's contribution to the worldwide assessment of existing chemicals.

Past changes to the Program have led to major improvements in the outputs, efficiencies and effectiveness of the Program (see Attachment A). For example, the Program has met and exceeded its target of completing 50 chemical assessments over 3 years. At the same time, the Program has also introduced a much broader range of activities in response to stakeholder needs. However, it is evident that there is still room for improvement in the Program.

Risk assessments continue to be resource intensive. With the introduction of a broader range of assessment types, the number of assessments has dramatically increased. However, there are still a very large number of chemicals that have not been assessed and for which there is no readily available information. In addition, the type of assessment selected for a chemical has not always been the most appropriate.

The Australian High Volume List has provided NICNAS and the community with information on volume and use of the bigger commodity chemicals. However, we know little about the remaining (approximately 38,000) industrial chemicals on AICS, making it difficult to select and prioritise chemicals for assessment.

Strategic alliances with several peak bodies have been established. These alliances need to be strengthened further to ensure improved uptake of recommendations resulting in whole of government efficiencies and to ensure that the Program appropriately addresses their priorities.

6. Overseas Trends in Assessment of Existing Chemicals

Risk assessment has been the primary focus of most national, regional and international existing chemicals programs. However, governments and international agencies have recently acknowledged the shortcomings in their risk assessment programs and general approach to chemicals management. The principal shortcomings identified include:

- the practice of undertaking risk assessments is too slow and resource-intensive and is only performed on a few priority chemicals;
- there is still insufficient knowledge on the health and environmental toxicity and risks of most chemicals on the market; and
- the lack of human and environmental exposure data is a major problem for completing risk assessments.

This realisation has led several governments and international agencies to review their programs and reposition themselves to better utilise their resources for chemical assessment with the aim of providing greater protection of human health and the

environment. Initiatives currently being considered or undertaken to address the above shortcomings include:

- refocusing assessment programs from risk assessments to hazard assessments;
- placing more responsibility on industry, rather than governments, to undertake chemicals testing, hazard and risk assessments;
- finding more effective ways to obtain information on volume, use and exposure to chemicals;
- introducing new ways to prioritise chemicals and identify chemicals that warrant risk assessment; and
- focusing on specialised issues, such as susceptible populations and newly recognised health and environmental effects.

7. The challenges

The Program needs to be a responsive and flexible program that meets national needs and priorities of our stakeholders while ensuring efficient and effective utilisation of resources.

Due to the limited resources available and the large number of existing chemicals in use in Australia, NICNAS needs to ensure efficient use of resources. In order to do this, the level of assessment should be commensurate with the level of risk posed by a chemical and the potential impact the type of assessment can have on environmental and human health and safety.

Issues for us to consider are:

- how do we identify which chemicals have the potential for the highest risk?
- what are the important issues for these chemicals?
- what NICNAS activity will address these issues and hence have the greatest impact?

The refocus of overseas assessment programs will see a rapid growth of available information on existing chemicals. The challenge will be how best to use this information to maximise efficiencies, reduce duplication and provide chemical information in a form that will be useful to stakeholders. The Program will need to find ways of sharing and integrating information relevant for chemicals management and ensuring its accessibility, dissemination and usefulness for different users.

One of the major barriers for the assessment and risk management of existing chemicals is identifying which chemicals are used in Australia, in what volume and for what uses. Finding this information on an individual chemical basis is very resource intensive. Are there more efficient ways to collect this information? Can the information also meet the public's need to know what chemicals are in use and which ones they may be exposed to?

One Program measure adopted by NICNAS is the monitoring of the uptake of recommendations made in PEC reports. Are there other indicators we can measure?

National assent will be required if we are to make informed decisions as to our position on certain globally restricted chemicals. Hence, the relevance of PEC assessments will increase if Australia ratifies the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC) and the Stockholm Convention on Persistent Organic Pollutants (POPs).

Possible outcomes of the review are:

- the Program is undertaking the right activities at the right level and only fine tuning of the Program is required; or
- the Program is undertaking the right activities overall, but there needs to be greater flexibility and increased outputs to meet the demands of the stakeholders; or
- the current activities are not relevant today and there needs to be a new approach.

8. How the review will be conducted

Steering Committee

A steering committee comprising a representative from NICNAS, industry, states/territories, the community, unions, Environment Australia and NOHSC will be set up to oversee the review.

Focus consultations

To ensure identification of options from a range of stakeholders, it is planned to meet with targeted groups from industry, Commonwealth and States/Territories governments and Non-Government Organisations. Their views on possible options for the Program will be sought.

Options Paper

An options paper will be developed taking into consideration the inputs provided from the focused consultations. This Options Paper will be disseminated widely as there are benefits to be gained by all parties from a broad level of participation.

Public Consultation

The Options Paper will be available to stakeholders for a period of two months. In the first month of release, meetings will be held in the major capital cities to meet with interested parties to discuss the Options Paper and clarify any issues.

Reforms agreed

Based on the discussions at the public consultation meetings and the written submissions, the various options identified for the Program and impact analysis of the options will be prepared. A new Existing Chemicals Program will be established that is consistent with NICNAS's commitment to continuous improvement and reduction of regulatory burden and ensuring adequate standards of protection.

History of the Existing Chemicals Program

	Changes to the Program	Outputs*
1990 - 1998	<p>1990: NICNAS established on a 50% cost recovery basis – fees charged for Priority Existing Chemicals (PECs).</p> <p>1994: A review of the fee structure resulted in changes to the method of fee calculation for PECs to make it easier for companies introducing a PEC to share the cost of the assessment.</p> <p>1995 – 1996: A Ministerial review of the effectiveness of NICNAS in the context of the move to full cost recovery. A shift in cost recovery policy was flagged with a more equitable burden for review being spread amongst a broad industry base being mooted</p> <p>1997 – 1998: Amendments to the <i>Industrial Chemicals Notification and Assessment Act 1989</i> to streamline the Program and to assist moving to full cost recovery. The intent was to provide for a stronger, enhanced Program by removing the cost impediment to companies and to increase the number of chemicals reviewed, which was driven by community demand for more information on chemicals.</p> <p>The changes led to:</p> <ul style="list-style-type: none"> • Removal of assessment fees for PECs as this was found to be inefficient with the potential to create market distortions. • Establishment of a system of company registration to fund the assessment of existing chemicals. • The introduction of greater flexibility in collecting information about candidate existing chemicals and in the declaration of PECs, enabling groups of chemicals to be assessed together and for preliminary assessments. • A streamlining of the process for preparation and review of assessment reports. 	7 (in 7 years)
1998 – 2001	April 1998: An enhanced Program was established with a commitment to achieve 50 chemical assessments (10 full and 40 preliminary assessments) over the following 3 years.	55 (in 3 years)
2001- to date	NICNAS sets an annual target of maintaining the same output which, on a pro rata basis equates to 3 full and 13 preliminary/other assessments.	30 (in ~2 years)
2003	The legislative changes have been in operation now for 5 years and it is now timely to revisit the Program.	

* assessments