

## Workshop Report

### NICNAS workshop on options for the framework for the assessment against risk-based criteria and prioritisation of chemicals on the Australian Inventory of Chemical Substances (AICS)

Friday 3 December 2010

#### Background

NICNAS is currently implementing the recommendations from the Review of the Existing Chemicals Program<sup>1</sup> (EC Review) pertaining to screening and prioritisation of chemicals on the Australian Inventory of Chemical Substances (AICS). This work will also address a part of the related recommendation from the Productivity Commission Research Report into Chemicals and Plastics Regulation<sup>2</sup>

Over the past two years, NICNAS has been actively working with its stakeholder advisory groups assisting with the implementation of the recommendations from the EC Review to develop options for a framework for the implementation of these recommendations.

A multi-stakeholder workshop to gain views of stakeholders on options for aspects of the framework was held in Sydney on the 3<sup>rd</sup> of December. The workshop was structured around a Discussion Paper (Attachment 1) provided to workshop attendees in advance that outlined three options for determining exposure to chemicals in Australia and examined some of the impacts of each option. The workshop provided opportunity:

- To explore options for a risk-based framework for the prioritisation of the AICS with a focus on efficient options for obtaining and using information to determine the potential for exposure of the Australian community and environment to the chemicals on AICS;
- To gain views from stakeholder groups; and
- For stakeholders to ask questions and understand each others views/positions.

Representative from industry, industry associations, scientific experts, community, state and territory government, the Australian government and NICNAS attended the workshop and the attendee list is attached (Attachment 2). Workshop groups were arranged according to sectors, with representatives from similar stakeholder sectors seated together. The rationale for this seating arrangement was to clearly identify responses and views from each stakeholder group. NICNAS representatives and scientific experts were seated across each of the groups to provide assistance and guidance with the workshop discussions.

The Workshop was divided into three parts, with an introductory presentation by the NICNAS Director followed by the first workshop session focusing on the questions raised in the discussion paper and the strengths and drawbacks of each option. The second workshop session focused on the order of preference of the three options presented taking into account the views provided in the first workshop. The agenda (Attachment 3) and a copy of the presentation (Attachment 4) are attached.

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<sup>1</sup>[http://www.nicnas.gov.au/About\\_NICNAS/Reforms/Review\\_Of\\_The\\_Existing\\_Chemicals\\_Program/EC\\_Review\\_FINAL\\_REPORT.pdf](http://www.nicnas.gov.au/About_NICNAS/Reforms/Review_Of_The_Existing_Chemicals_Program/EC_Review_FINAL_REPORT.pdf)

<sup>2</sup> [http://www.pc.gov.au/\\_\\_data/assets/pdf\\_file/0017/82331/chemicals-plastics-regulation.pdf](http://www.pc.gov.au/__data/assets/pdf_file/0017/82331/chemicals-plastics-regulation.pdf)

The presentation provided the participants with background information and an overview of the discussion paper. This included:

- The origin of the related Existing Chemicals Review and Productivity Commission Report
- Similar activities currently underway overseas
- The proposed overall risk-based approach for assessing chemicals on AICS
- Challenges in implementing the framework
- Overview and comparison of three options for provision of exposure indicator information by industry (summarised in Table 1).

**Table 1: Summary of exposure indicator information required from industry**

	Option A	Option B	Option C
First phase	Volume and use data for all chemicals in commerce	Identity of all chemicals in commerce	None
Second Phase	Some downstream use information	Volume and use information (including downstream use) for subset of chemicals	None
End of Prioritisation (information required for further assessment)	None*	None*	Volume and Use information (including some downstream use) on published lists of prioritised chemicals*

\* In some cases detailed exposure information may be required post-prioritisation for in-depth assessments

In the first workshop session attendees were asked to consider the questions that were raised in the workshop discussion paper in order to provide views on:

- “Fast tracking” groups of chemicals through the prioritisation to determine immediate risk management requirements
- The strengths and drawbacks of the three options for provision of exposure indicator information by industry.

This was followed by a reporting session where each stakeholder group was given the opportunity to present their responses and ask questions of NICNAS and other stakeholder groups.

In the second workshop session, each stakeholder group was asked to present their overall order of preference for the three options for collecting exposure information following discussions surrounding the collective workshop responses and views.

### **Outcomes from the workshop**

#### **“Fast Tracking” Groups of Chemicals**

The first issue discussed was whether the framework should be applied to allow for some groups of chemicals on the inventory to be “fast tracked” (i.e. addressed early in the project) to determine whether immediate risk management measures are required in Australia.

All stakeholder groups agreed that certain groups of chemicals should be considered ahead of the majority of chemicals on the national inventory. Stakeholders considered that chemicals introduced into Australia in high volumes, chemicals restricted overseas or chemicals found in people could be considered first in order to address those for which information is already held or which have already been identified as chemicals of concern.

### Options for provision of exposure indicator information by industry

#### *Strengths and drawbacks*

The collective views from all groups on the strengths and drawbacks of the options for provision of exposure indicator information by industry are provided in Table 2.

**Table 2: Strengths and drawbacks of options**

	Strengths	Drawbacks
Option A	<ul style="list-style-type: none"> <li>• Use of Australian exposure data upfront</li> <li>• Information more accurate as based on Australian data</li> <li>• Results in smaller number of priorities (refined list) for further assessment</li> <li>• Most cost effective for NICNAS</li> <li>• One data call from industry</li> </ul>	<ul style="list-style-type: none"> <li>• Provision of volume/use information problematic for some companies</li> <li>• Costly for industry to provide exposure information and all data not useful in identifying chemicals of concern</li> <li>• Time taken to provide exposure information</li> <li>• Highly reliant from data from industry – potential for incomplete volume and use data</li> </ul>
Option B	<ul style="list-style-type: none"> <li>• Results in smaller number of priorities (refined list) for further assessment</li> <li>• Knowledge of identity of chemicals used required under existing regulations</li> <li>• Can target calls for information directly to those introducing the chemical rather than general list-based calls for information</li> <li>• Less costly to NICNAS than Option C</li> <li>• Less costly to industry to provide data than Option A</li> </ul>	<ul style="list-style-type: none"> <li>• Industry wants as many chemicals as possible screened for hazard/risk to allow substitution with low risk chemicals.</li> <li>• More work, and hence a higher cost, for NICNAS than option A</li> <li>• More costly for industry to provide data compared with option C/possible 2nd call for data</li> </ul>
Option C	<ul style="list-style-type: none"> <li>• All chemicals evaluated -hence provides industry information for substitution</li> <li>• This option does not rely on industry information to commence work</li> <li>• Initial industry costs minimised but overall costs could be higher</li> </ul>	<ul style="list-style-type: none"> <li>• All chemicals evaluated - hence requires more resources</li> <li>• Results in larger number of priorities given the use of conservative assumptions</li> <li>• Most resource intensive option for NICNAS</li> <li>• Once priority chemicals published</li> </ul>

		<p>creates a perception that is hard to change</p> <ul style="list-style-type: none"> <li>• Potential damage to reputation of industry as not willing to provide exposure info.</li> <li>• There could be delays in completing the work due to revisiting assessments as industry may provide actual data once a chemical is prioritised.</li> </ul>
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### ***Order of preference***

- Overall (consensus), option A was least favoured by stakeholder groups because of practicality issues.
- Community and State Government representatives preferred option B over C due to its cost effectiveness and the outcome of a smaller and refined set of priorities. Community representatives noted that in principle they preferred option A but this was given a lower order of preference considering that the industry information required could not be collected via a mandatory requirement at present.
- Australian Government representatives did not have a clear preference for option B or C, however there was a consensus in the need to proceed with the project as soon as practical.
- Representatives of companies preferred option B or C or a variant of these options depending on the nature of their systems and the capacity to readily access the required information.
- Industry Association representatives did not rank the options and commented on a need to use priority lists identified elsewhere and avoid duplication of prioritisation efforts.

### ***Further Messages/Other Suggestions Raised***

- Industry representatives suggested that hazard information for as many chemicals as possible on the inventory be determined to allow substitution with low risk chemicals
- Options could be enhanced by giving industry opportunity/incentives (e.g. recognition) to provide more detailed information at an earlier stage.
- Certain stakeholders also suggested regular update of the inventory (as occurs in some countries) and consideration of a mandatory requirement to provide exposure information to ensure a level playing field for all companies.

### ***Next steps***

The views from this workshop have been discussed with the NICNAS stakeholder advisory group assisting with the implementation of recommendations from the EC Review and will be taken into as the overall framework for the assessment and prioritisation of chemicals on the Australian Inventory of Chemical Substances (AICS) is developed.

## **Discussion paper for the workshop on options for the framework for prioritisation of the AICS (December 2010)**

### **Background**

Several of the recommendations from the Review of the Existing Chemicals Program and Recommendation 4.6 from the Productivity Commission (PC) Research Report into Chemicals and Plastics Regulation relate to the prioritisation of all chemicals on the Australian Inventory of Chemical Substances (AICS). Implementation of the outcomes from the Review of the Existing Chemicals Program was agreed by subsequent governments.

NICNAS has been actively working with its stakeholder advisory bodies and other key stakeholders to establish a framework for the prioritisation of the AICS that is scientifically robust and as cost effective and efficient as possible for NICNAS, industry and other stakeholders. A workshop of industry representatives was held late last year to discuss the mechanics of collecting information on identity, volume and uses of chemicals imported/manufactured. The information on industry practices and capabilities gained from this workshop was utilised in the development of a broad range options for the framework for prioritisation.

Whilst the NICNAS stakeholder advisory groups assisting with the implementation of the Existing Chemicals Review have supported a risk based approach to the prioritisation of the AICS, a final framework has not been decided.

This workshop will explore options for a risk-based framework for the prioritisation of the AICS with a focus on efficient options for obtaining and using information to determine the potential for exposure of the Australian community and environment to the chemicals on AICS.

Three possible risk based options are discussed in this paper, two based on options developed in conjunction with the stakeholder advisory bodies (options A and B) and one (option C) which has been subsequently been developed.

Information arising from this workshop will be considered by NICNAS and its stakeholder advisory bodies in the development of a preferred framework.

### **What is prioritisation?**

Prioritisation is the tiered assessment of chemicals on the AICS against human health hazard, environmental and exposure indicator criteria to determine those chemicals that are not expected to pose concern to workers, public health and the environment and those that are considered to require further assessment to determine their risk and recommend risk mitigation measures to ensure safe use. This tiered assessment will also provide a ranking for those chemicals that are considered to require further assessment. Chemicals that are determined not to pose a concern would be re-examined if new information that indicates a concern becomes available.

The first phase of the tiered assessment (first phase assessment) is a high throughput approach using tabulated electronic data (that is either publicly available or that can be readily generated using Quantitative Structure Activity Relationship modelling), that can efficiently be applied to the health, environmental and exposure indicator criteria for all chemicals on the AICS. Sources of information that can only be extracted on chemical by chemical basis are not suitable for use in the first phase.

First phase assessment constitutes a complete assessment for those chemicals that are determined not to pose a concern to human health and the environment according to the risk criteria established for prioritisation. These chemicals will not be considered further unless new information that indicates a concern becomes available. First phase assessment information will be published for these chemicals.

Chemicals for which this determination cannot be made will undergo further assessment.

The second phase of the tiered assessment (second phase assessment) is undertaken in a chemical by chemical manner using publically available sources of hazard data and exposure information. Second phase assessment will be used to refine inputs for risk characterisations made in the first phase assessment to identify additional chemicals that are not expected to pose a concern to workers, public health and the environment based on the available data and therefore not require further assessment.

Chemicals for which this determination cannot be made will be prioritised (ranked) for further assessment. Second phase assessment information will be published whether or not the chemical is prioritised for further assessment.

### **Challenges**

Amongst the challenges is accessing both hazard and exposure indicator information (that is, volume of the chemical manufactured/imported and the use of the chemical) required to undertake a risk-based prioritisation.

An analysis of chemicals on AICS indicates that only limited hazard information is available for more than 80 per cent of all listed chemicals. NICNAS will group chemicals to allow read-across of data from data rich to data poor chemicals and use predictive modelling where possible when toxicity data are not available. NICNAS is enhancing its capability in this area and will be utilising these approaches in a trial hazard evaluation being undertaken on 1000 randomly chosen AICS-listed chemicals. It is expected that hazard data on a larger number of chemicals will come available with the publication of REACH dossiers. NICNAS is currently conducting an analysis of the REACH dossiers as they become available to determine the extent to which the information can be utilised.

Volume and use information data were not collected when the inventory was established. Although volume and use information has been collected on a limited number of chemicals i.e. those introduced in high volumes, this information is not available for a large majority of AICS-listed chemicals. In addition, as almost two decades have passed since AICS was compiled, there is also a strong possibility that many of the listed chemicals are no longer used in Australia.

Industry has expressed concerns about the costs and difficulty of providing identity, volume and use data due to the design of company information recording systems and confidentiality matters. NICNAS currently does not have mandatory powers in relation to collecting exposure information on all chemicals in commerce and therefore would need to rely on cooperation from industry.

Given these challenges and the large number of chemicals on the AICS it is important that the risk-based approach will:

- allow chemicals for which data is difficult to obtain to be treated consistently with those for which data is readily available, and
- be able to be efficiently applied across the large number of chemicals.

### Overall risk-based approach

A risk matrix approach will be utilised to assign the chemicals on the AICS into groups of chemicals that are considered to have a similar priority for further assessment on the basis of their risk.

This approach:

- takes into account both hazard and exposure information;
- utilises hazard and exposure bands within the matrix to enable the risks of a large number of chemicals to be determined consistently;
- can be applied consistently for a variety of exposure indicator information (actual, surrogate or default); and
- can equally be applied in the first and second phase of the tiered assessment.
- will be applied separately to determine the potential risk to human health and the environment.

Under this system, the potential for exposure will be determined based on available exposure indicator information. The chemicals would be assigned to an exposure band and a determination would be made on the basis of risk depending on the hazard band that has been assigned. The higher the exposure band (i.e. the greater the exposure) the lower the hazard profile (hazard band) required to prioritise a chemical. Figure 1 shows how this system would apply.

**Figure 1: Risk-based approach for prioritisation**

Increasing Exposure →

		Exposure band				
		0 (no exposure)	1	2	3	4
Increasing Hazard ↓	0 (no indication hazard)	Not Prioritised				
	1	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised
	2	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised	Prioritised
	3	Not Prioritised	Not Prioritised	Prioritised	Prioritised	Prioritised
	4	Not Prioritised	Prioritised	Prioritised	Prioritised	Prioritised

***Allocation of exposure band***

The potential for exposure can be estimated using information on the amount of an individual chemical being introduced into Australia, and the uses of the chemical.

A use category and a volume will be assigned to each chemical, using information available to NICNAS. This may be actual information, surrogate information or default approaches depending on the framework option implemented. An exposure score (an estimate of the total volume available for exposure) is then derived by applying a multiplier (derived from the use category) to the total volume:

$$\text{EXPOSURE SCORE} = \text{VOLUME} \times \text{USE MULTIPLIER}$$

The chemicals are then assigned into a number of decreasing exposure bands by applying cut-offs to the exposure score ranking. It is proposed that 4 bands (plus a 'zero band' for not in use) are used.

***Determining values for use multipliers***

The basis for determining the use multiplier is proposed to be the fraction of the total introduced chemical which is available for exposure. Where data is derived from a range of sources, a simplified weighting system using a logarithmic scale is considered to be most applicable.

Use multipliers may differ for human and environmental exposure. For simplicity, occupational and public exposure would be considered together with the highest multiplier being applied. The use of a small number of multipliers simplifies the task of assigning multipliers for information derived from a range of sources.

The concept of the use multiplier can best be explained by considering some examples at opposite ends of the spectrum. Where a chemical is introduced under controlled conditions and consumed e.g. as an isolated reaction intermediate, possibly a maximum of 0.1% of the volume would be available for human exposure and the relevant use multiplier would be 0.001. If, however, a chemical is introduced in a face cream, it may be assumed that 100% is available for exposure and the relevant use multiplier would be 1.

Assignment of multipliers for the wide range of uses of industrial chemicals could be undertaken in consultation with a group of experts. Default volume values which would be based on High Volume Industrial Chemical reporting thresholds could also be discussed with this group of experts.

***Allocation of hazard band***

In parallel to this the human health and environmental hazards would be assigned into an equal number of bands as exposure either on the basis of specific endpoint combinations, or on the basis of a combined hazard score. The hazard bands would be appropriately aligned with the exposure bands. Similar to the exposure bands, a "zero band" would be assigned where the hazard criteria were not met.

**Options for the framework for prioritisation of the AICS**

Three possible options for the framework for prioritisation of the AICS are presented below. Options A, B and C are all based on the same overall risk based approach (described above) where exposure and hazard bands are assigned to chemicals to enable prioritisation on the basis of risk.

***Activities Common to all options***

The hazard based work and other aspects of the framework to improve efficiency are identical for the three options. This includes:

- Certain classes of chemicals will be removed upfront i.e. those, that have previously been assessed by NICNAS and those that can easily be predicted to be in the “zero band” for hazard, e.g. Polymers of Low Concern (PLCs) and obvious low concern chemicals;
- Overseas data for hazard and use will be used in the first and second phase assessment where available
- Read-across approaches and predictive modelling will be used where possible when toxicity data are not available;
- Chemicals determined not to pose a concern will be cross checked against national/international lists of high priorities as a precaution.
- First and second phase assessment information will be published.

Whilst the framework will be applied to all chemicals on the AICS, it has previously been agreed that as exposure information is held by NICNAS on approximately 800 high volume chemicals, the framework will be first applied to this subset of AICS chemicals, under any option, to provide early outcomes.

There may be other groups of chemicals that may be considered candidates for which a similar fast tracking would be advantageous to determine whether immediate risk management measures are required in Australia. Examples include chemicals that are restricted or are currently undergoing risk management overseas or chemicals for which there are concerns due to levels found in people or the environment. In the event that information on volume and use is not being provided by industry, a call for information on these chemicals would be required to progress these chemicals to risk management at an early stage.

**QUESTION 1:** Provide views on whether prioritisation should be organised such that some groups of chemicals are fast tracked to determine whether immediate risk management measures are required in Australia?

***Exposure Indicator Information***

The information required to be provided by industry (summarised in Table 1 and described under each option below) differ for each option.

***Option A***

Option A requires industry to provide NICNAS with volume and use information for all chemicals introduced by each company at an early stage. Once this information is compiled, a large number of chemicals are expected to be identified as not in use and assigned to the “zero band” for exposure.

Chemicals in commerce will undergo a risk based assessment in the first phase of the tiered assessment with the assigned exposure band based on actual data. NICNAS will then undertake a more resource intensive chemical by chemical evaluation of the hazard on those chemicals that require second phase assessment to refine inputs for hazard band assigned in the first phase assessment to determine the list of final priorities.

Due to collection of information on the volume and use of the chemicals in the first phase, it is likely that no further information will need to be collected in the second phase for the majority of chemicals. However, there will be a subset of chemicals, particularly those sold on to reformulators, where uses may not be identified by the introducer in the first phase. For these chemicals, downstream use information may be needed in the second phase of the tiered assessment.

### *Option B*

Option B requires industry to provide NICNAS with information to identify all chemicals that they introduce at an early stage. Once this information is compiled, a large number of chemicals are expected to be identified as not in use and assigned to the “zero band” for exposure.

Chemicals in commerce will undergo a risk based assessment in the first phase of the tiered assessment with the assigned exposure band based on surrogate use data such as use data from overseas sources, or default values where actual or surrogate data is not available. A default volume based on the number of importers will be used where actual data is not available.

NICNAS will then undertake a more resource intensive chemical by chemical evaluation involving both hazard and use data on those chemicals that require second phase assessment to refine inputs for hazard and exposure bands assigned in the first phase assessment to determine the list of final priorities.

Surrogate use information including industry sector information for the companies known to be introducing the chemical will be used where available. Depending on the hazards of the chemical, volume and use information will be sought directly from companies who indicated that they are introducing the chemical where potential risk cannot be confidently established from information available. This would be a more efficient process than more general calls for information on lists of chemicals. Downstream use information may be sought on a subset of chemicals.

### *Option C*

Under this option, industry would not be required to provide information on the chemicals they are introducing at an early stage. NICNAS may undertake a call for information for chemicals on AICS that are suspected to not be in use for industrial purpose, such as known pesticides and medicines, so that these chemicals can be set-aside.

All chemicals on the AICS (except those that can be determined as not expected to pose concern to workers, public health and the environment at an early stage) will undergo a risk based assessment in the first phase with the assigned exposure band based on surrogate use data such as from overseas sources, or default values where actual or surrogate data is not available. As the number of importers would not be known the most conservative default volume will be used for the majority of chemicals.

NICNAS will then undertake a more resource intensive chemical by chemical assessment on those chemicals that require second phase assessment using surrogate data or default values to refine inputs for hazard and exposure bands assigned in the first phase assessment to determine the list of final priorities.

NICNAS will publish lists of prioritised chemicals together with the prioritisation assessment information. Recommendations to risk management agencies may be able to be made on the basis of this assessment information. If further assessment is required, volume and use information including downstream use information which could be used to revise the risk based determination for prioritisation will be sought as part of the further assessment of these chemicals. This information will be sought from industry through list based calls for information. Based on the Canadian experience with a similar project it is expected that several thousands of chemicals would be prioritised. Therefore, a number of lists of > 500 chemicals will need to be published.

Throughout the first and second phase assessment process industry will have the opportunity to voluntarily provide relevant information that can be utilised by NICNAS to revise conservative default assumptions, resulting in more realistic risk-based determinations.

**Table 1: summary of exposure indicator information required to be provided by industry**

	Option A	Option B	Option C
First phase	Volume and use data for all chemicals in commerce	Identity of all chemicals in commerce	None
Second Phase	Some downstream use information	Volume and use information (including downstream use) for subset of chemicals	None
End of Prioritisation (information required for further assessment)	None*	None*	Volume and Use information (including some downstream use) on published lists of prioritised chemicals*

\* In some cases detailed exposure information may be required post-prioritisation for in-depth assessments

**QUESTION 2:**

Provide views on the **relative** feasibility of providing:

- information to identify all chemicals that a company introduces ;
- volume information for chemicals in commerce; and
- use information for chemicals in commerce

**QUESTION 3:**

Provide views on the **relative** benefits and feasibility of the following mechanisms by which information could be sought from industry:

- List-based approach i.e. publication of several lists requesting information for a large number of chemicals (>500 chemicals each);
- targeted requests for information from companies known to be introducing a chemical; and
- whole of inventory approach i.e. information provided on all chemicals introduced by a company.

**QUESTION 4:**

Are there any other options available to estimate potential exposure to chemicals on the AICS?

**Conservatism of Risk Assessment**

The potential for the risk to be overestimated increases as the reliance on conservative default values to assign an exposure band increases.

The potential for the risk to be overestimated and hence the number of chemicals in the final list of priorities is expected to be similar for option A and option B.

A major difference between option B and option C is the identification of chemicals that are not in use in Australia and the ability to obtain information to refine the risk characterisation directly from the company introducing a chemical. Therefore the number of chemicals in the final list of priorities will be higher for option C compared with Option B due to the increased reliance on conservative default values to assign an exposure band.

**QUESTION 5:** What are the implications of publishing a final list of priorities containing chemicals for which the risk may have been overestimated on the basis of using conservative default values?

**Indicative Cost of Additional NICNAS Resources Required**

The cost of the additional NICNAS resources required for Options A, B and C are listed in Table 2. This is based on the assumption that a proportion of existing NICNAS resources will be available to undertake prioritisation related activities.

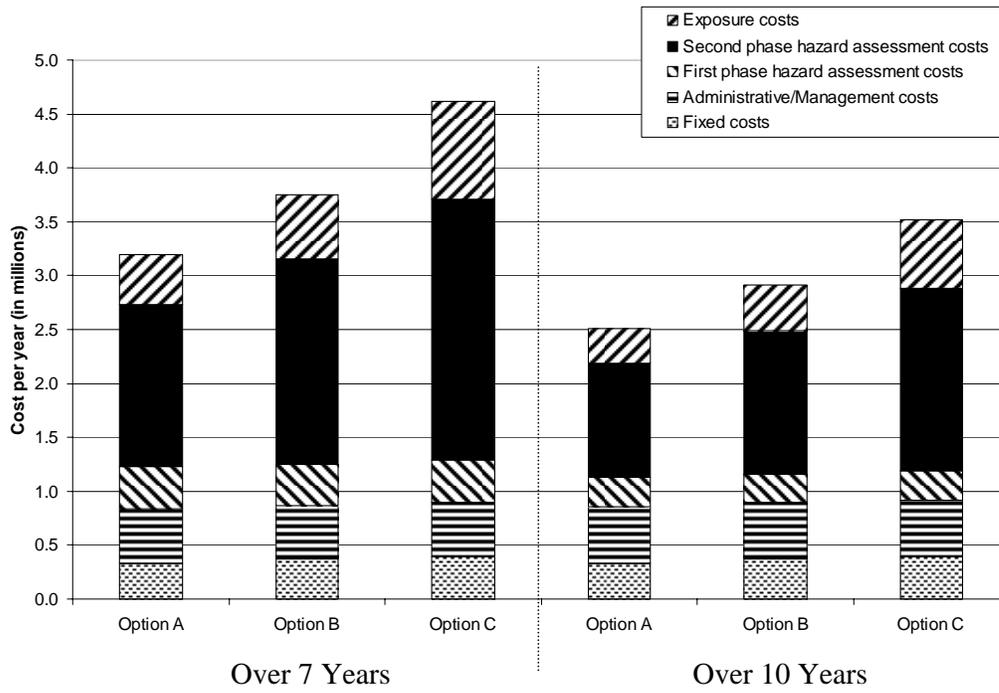
**Table 2: Estimates of NICNAS Costs for Options A, B and C**

	<b>Option A</b>	<b>Option B</b>	<b>Option C</b>
Cost of additional NICNAS resources required per annum over <b>7 years</b>	3.2 million	3.8 million	4.6 million
Cost of additional NICNAS resources required per annum over <b>10 years</b>	2.5 million	2.9 million	3.5 million

The estimates indicate that the yearly cost of the project is approximately 0.009 – 0.017% of the annual value of chemicals introduced (i.e. manufactured and imported) to Australia. This is based on an annual chemical introduction value of \$26.5 billion for the NICNAS registration year of 2009/10 calculated from data provided by registrants.

A breakdown of the costs for each option is illustrated in Figure 2. Cost estimations are presented for a project timeframe of 7 and 10 years. The most resource intensive component of the project is the second phase hazard assessment followed by the exposure assessment of chemicals. Second phase costs increase with the number of chemicals that need to be assessed.

**Figure 2: The Cost Breakdown of Each Option**



**Attendees**

**NICNAS Workshop on options for the framework for the assessment against risk-based criteria and prioritisation of chemicals on the Australian Inventory of Chemical Substances (AICS)  
Friday 3 December 2010**

Industry:

Pierre Debets	<i>Mobil Oil Australia Pty Ltd</i>
Bruno Lorizio	<i>Brother International (Aust) Pty Ltd</i>
Julie Newlands	<i>Unilever Australia Pty Ltd</i>
Robert Parbery	<i>Johnson &amp; Johnson Pacific</i>
Phillip Tudor	<i>Huntsman Corporation Australia Pty Ltd</i>

Industry Association:

Graeme Haley	<i>Engel, Hellyer &amp; Partners Pty Ltd</i>
Geoff MacAlpine	<i>PACIA</i>
Dusanka Sabic	<i>ACCORD Australasia</i>

Scientific Experts:

Milton Hearn	<i>Monash University</i>
Ian Rae	<i>University of Melbourne</i>
Suzie Reichman	<i>RMIT University</i>

Community:

Jane Bremmer	<i>Australian Environmental Network</i>
James Courtney	<i>Australian Environmental Network</i>
Pamela Grassick	<i>Queensland Council of Trade Unions</i>
Mariann Lloyd-Smith	<i>National Toxics Network</i>
Renata Musolino	<i>Australian Council of Trade Unions representative</i>
Barry Pratt	<i>Barry Pratt &amp; Associates</i>
Rye Senjen	<i>Monash University</i>

States & Territories:

Anita Aiezza	<i>Worksafe Victoria</i>
Therese Manning	<i>NSW Department of Environment, Climate Change and Water</i>

Commonwealth:

Richard Barker	<i>Department of Innovation, Industry, Science and Research</i>
Les Davies	<i>Australian Pesticides and Veterinary Medicines Authority</i>
Raj Pathya	<i>Department of Defence</i>
David Perry	<i>Department of Sustainability, Environment, Water, Population &amp; Communities</i>
Wayne Simpkins	<i>Australian Customs and Border Protection Service</i>
Megan Watson	<i>Department of Innovation, Industry, Science and Research</i>

NICNAS:

Bill Diver  
Bob Graf  
Matt Gredley  
Marion Healy  
Roshini Jayewardene  
Malsha Kitulagodage  
Kerry Nugent  
Farah Reza  
Justin Roberts  
Sneha Satya  
Phillip Sharp  
Louise Stedman  
Sami Syed  
Janith Wickramaratna



**Prioritisation of Chemicals on the AICS  
 Workshop  
 3 December 2010  
 9:30 am - 4:30 pm**

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**Lyceum Room, Wesley Conference Centre  
 220 Pitt Street, Sydney NSW 2000**

<b>1</b>	<b>Welcome</b>	9:30 – 10:00	Facilitator
<b>2</b>	<b>Presentation on Prioritisation</b>	10:00 – 11:00	Dr. Marion Healy
	<i>Morning Tea</i>	11:00 – 11:15	
<b>3</b>	<b>Briefing for the workshop</b>	11:15– 11:30	Facilitator
<b>4</b>	<b>Workshop session 1 - discuss options and discussion paper</b>	11:30 - 12:15	All
<b>5</b>	<b>Reporting session 1</b>	12:15 - 12:45	All
	<i>Lunch</i>	12:45 - 1:30	
<b>6</b>	<b>Reporting session 2</b>	1:30 - 2:00	All
<b>7</b>	<b>Question time</b>	2:00 - 2:15	All
<b>8</b>	<b>Workshop session 2 - discuss results from workshop 1</b>	2:15 - 3:00	All
	<i>Afternoon Tea</i>	3:00 - 3:15	
<b>9</b>	<b>Debrief + Summary</b>	3:15 - 4:00	Facilitator
<b>10</b>	<b>Wrap-up and Next Steps</b>	4:00 – 4:30	Dr Marion Healy

 Australian Government  
Department of Health and Ageing  
NICNAS

Regulating chemicals for your protection

## Accelerated Assessment of the National Inventory

**Dr. Marion Healy**  
Director

 Australian Government  
Department of Health and Ageing  
NICNAS



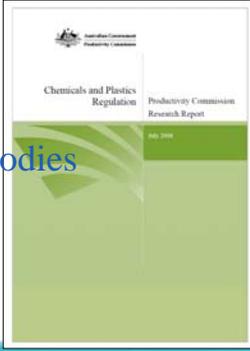
### Purpose of the Workshop

Gain views of stakeholders on the options for  
the framework for the assessment of  
chemicals on the national inventory against  
risk-based criteria

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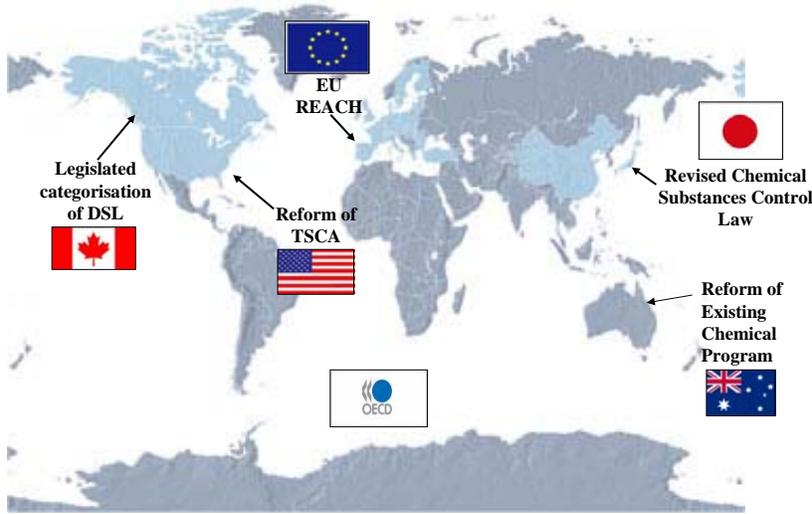
## Background

- Existing Chemicals Review- 2006
- Implementation agreed by subsequent Governments
- The Productivity Commission- 2008
- Extensive consultation with Advisory bodies and technical experts- Since 2008
- Stakeholder Workshop- 2009

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## Overseas Activities



Legislated categorisation of DSL

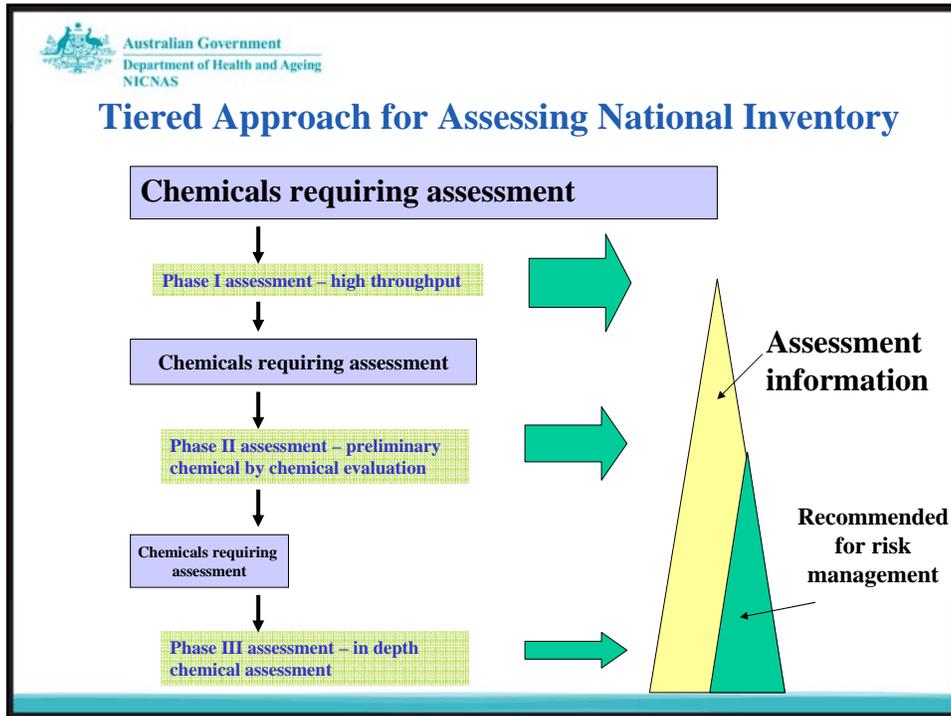
EU REACH

Reform of TSCA

Revised Chemical Substances Control Law

Reform of Existing Chemical Program

OECD



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## Phase I and II assessment

- First phase assessment is a high throughput approach that can be efficiently applied to all chemicals
  - Uses available tabulated exposure and hazard information or modelling data
- Second phase assessment is a preliminary chemical by chemical evaluation of hazard and exposure information
  - Uses publically available information
  - Refine inputs for risk characterisations made in first phase



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## Aims of Phase I and II Assessments

- Assess all chemicals on AICS against risk based criteria
- Identify chemicals that require immediate risk management
- Identify chemicals that require further assessment for their risk management
- Increase knowledge about the risks of chemicals in Australia
- Maintain alignment with comparable regulatory schemes
- Avoid duplication of effort



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## Challenges



- Size of inventory >38,000 chemicals
- Limited hazard information (public sources)  
>80% of chemicals on AICS are data poor
- Limited exposure information
  - volume and use data not collected when inventory established


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## Risk-Based Matrix Approach

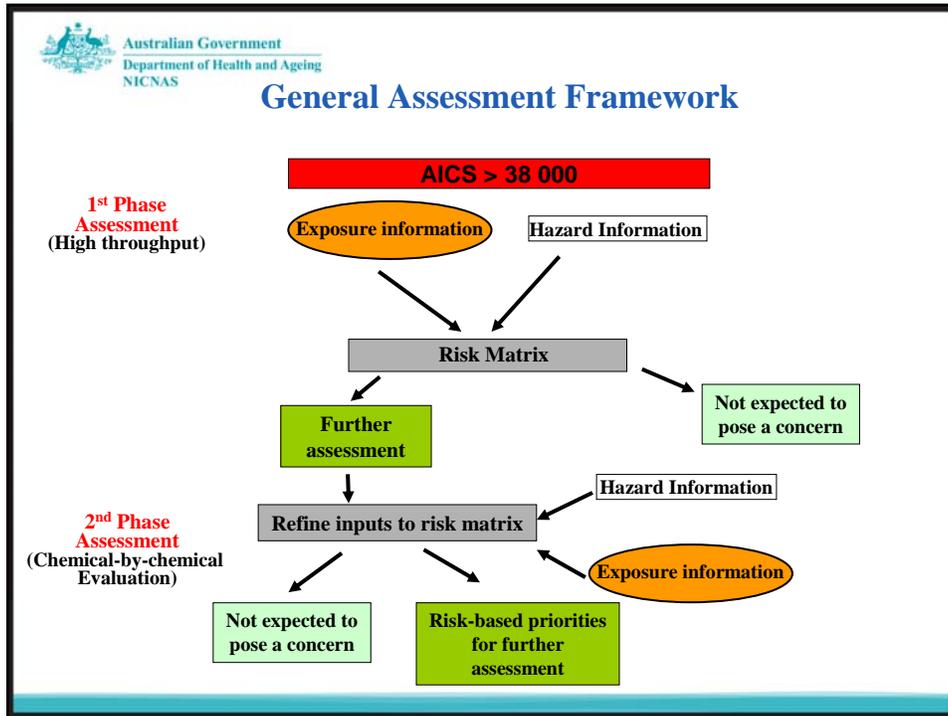
Increasing Exposure →

		Exposure Band				
		0 (no exposure)	1	2	3	4
Increasing Hazard ↓	0 (no indication hazard)	Not Prioritised				
	1	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised
	2	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised	Prioritised
	3	Not Prioritised	Not Prioritised	Prioritised	Prioritised	Prioritised
	4	Not Prioritised	Prioritised	Prioritised	Prioritised	Prioritised


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## Options for Framework

- Three options for risk-based framework
- Activities common to all options
  - Risk matrix approach
  - Tiered assessment
  - Certain classes of chemicals removed upfront
  - Overseas data used where available
  - Predictive approaches and modelling used where toxicity data not available
  - Assessment information will be published
  - Early outcomes for *High Volume Industrial Chemicals*

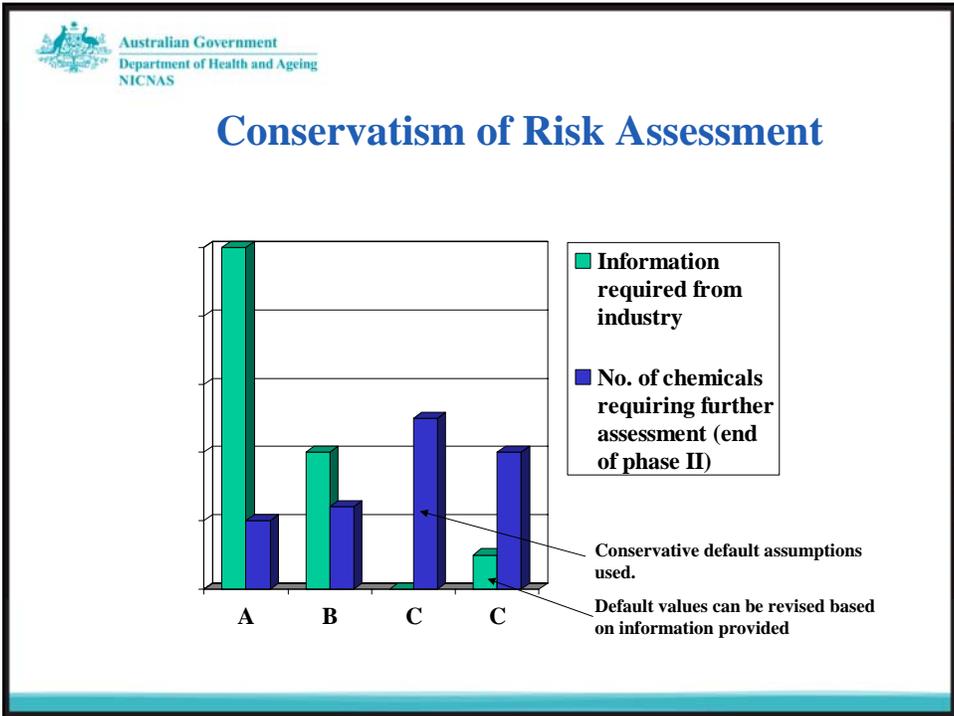
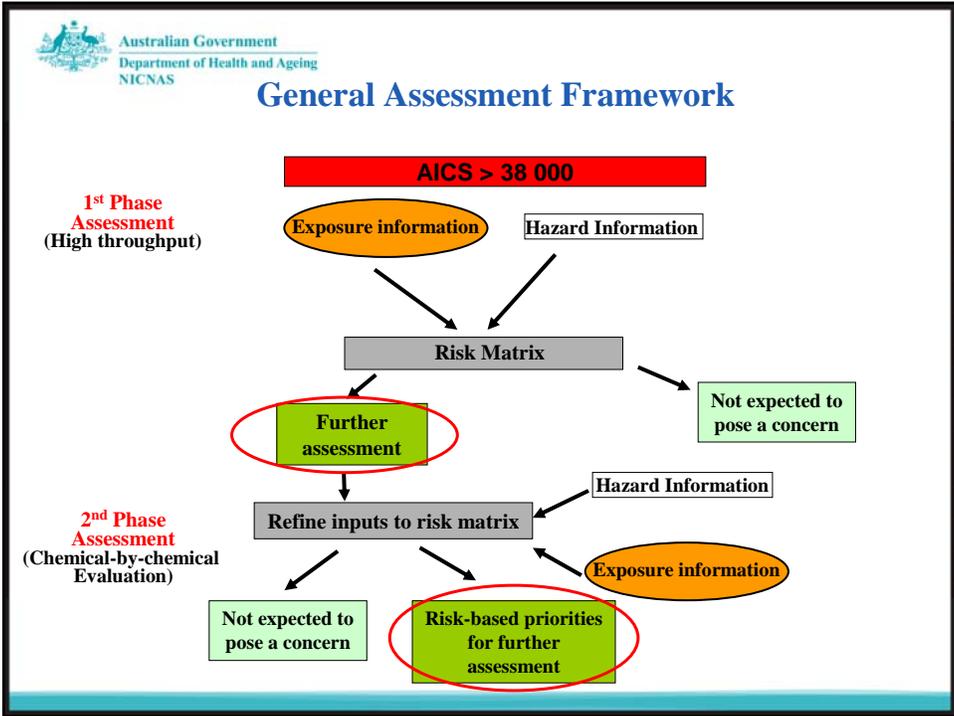



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## Exposure Indicator Information

	Option A	Option B	Option C
<b>First phase</b>	Volume and use data for all chemicals in commerce	Identity of all chemicals in commerce	None
<b>Second Phase</b>	Some downstream use information	Volume and use information (including downstream use) for subset of chemicals	None
<b>Information required for further assessment</b>	None*	None*	Volume and Use information (including some downstream use) on published prioritised chemicals*

\* In some cases detailed exposure information may be required for in-depth assessments





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## Cost Comparison for Options

	Option A	Option B	Option C
Cost of additional NICNAS resources required per annum over <b>7 years</b>	3.2 million	3.8 million	4.6 million
Cost of additional NICNAS resources required per annum over <b>10 years</b>	2.5 million	2.9 million	3.5 million

0.009 – 0.017% of the annual value of chemicals introduced to Australia



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