NICNAS SUBMISSION TO THE PRODUCTIVITY COMMISSION DRAFT RESEARCH REPORT ON CHEMICALS AND PLASTICS REGULATION

Introduction

This submission is in response to the Productivity Commission (PC) Draft Research Report (March 2008), and follows the Commission's proposed institutional and regulatory approach as follows:

1. Formulation of strategic policy and system oversight
2. Assessment of hazards and risks of chemicals
3. Risk management: standard setting and administration

Through this submission NICNAS provides comment on recommendations and observations contained in the draft Research Report and highlights some attendant issues for the PC's consideration.

1. Formulation of strategic policy and system oversight

NICNAS risk assessment comprises three sectors, occupational health and safety, public health and the environment as determined by legislation, the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act).

In practical terms, NICNAS undertakes its functions within the general policy frameworks developed by sector specific ministerial councils for occupational health and safety and public health. Some policy oversight is also provided by the Environment Protection Heritage Council that coordinates approaches to environmental impacts of chemicals. Policy formulation within each sector has been developed independently and coordination mechanisms have not been established. This presents some concerns for NICNAS when the assessment of a chemical raises issues that cut across sectors. The PC recommendation to establish a Standing Committee on Chemicals (PC Recommendation Rec 3.1) provides mechanism to address this concern and NICNAS welcomes further discussion on the implementation of such a mechanism.

2. Assessment of hazards and risks of chemicals

The overall Australian chemicals management framework has assigned the scientific risk assessment function to a national level. All conventional risk assessments of chemicals utilise the conceptual framework recommended by the National Academy of Sciences and the World Health Organisation (WHO)/International Program on Chemical Safety (IPCS) consisting of a four step scientific process: hazard identification, dose-response assessment, exposure assessment and risk characterization. This framework provides for a structured review of information relevant to evaluating human health or environmental outcomes from the use of chemicals. NICNAS conducts it's risk assessment function

within this internationally agreed framework and the outcome from the risk assessment is the basis for consideration of further action at Commonwealth and/or state/territory levels.

Risk analysis in a broad sense integrates risk assessment, risk management and risk communication activities. Risk management involves the evaluation of which risks identified through the risk assessment process require risk mitigation measures to ensure that those risks are managed. For industrial chemicals, national coordinating bodies and state/territory agencies predominantly undertake risk management functions, although some risk management functions are undertaken by NICNAS (under the Act). Risk communication involves interactive dialogue between stakeholders, risk assessors and risk managers, which in turn actively informs risk assessment and risk management processes. Risk communication is undertaken by both risk assessment agencies and risk management bodies usually in a sector specific manner. Collective these functions ensure the safe and sustainable use of chemicals.

Generating net public benefit

The draft PC report makes the observation that regulatory intervention should address market failures to the extent that it provides a net community benefit. To this end the PC recommends that the objective of NICNAS should be to maximise net community benefit and that its assessment requirements and outcomes should be supported by analysis of the associated costs and benefits (PC Recommendation 4.1).

The objects of the Act are predominantly to provide for a national system of notification and assessment of industrial chemicals for the purposes of:

- aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals; and
- providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals.

In undertaking it's risk assessment functions, NICNAS aims for the risk assessment effort to be commensurate with the hazard and/or exposure to the chemical, where this can be defined sufficiently in advance of the assessment. The reforms that have been progressively introduced into NICNAS's notification and assessment framework have sought to further this objective. This position is consistent with international protocols for risk assessment.

The Act compels notification and assessment on the introducer of chemicals, however it does not control downstream regulation or chemical management activities. It is predominantly at the stage of considering risk management measures for individual chemicals or groups of chemicals that the national coordinating bodies and states and territories consider the costs and benefits of specific measures. This is consistent with the

international frameworks under which risk management brings together the outcomes of the risk assessment and socioeconomic impacts of different options.

For the reasons outlined above, the exact intent of this recommendation needs clarification.

Separation of risk assessment and risk management functions
The Act and associated regulations have as a major objective risk assessment of industrial chemicals for the purposes of protecting Australian people and the environment. The Act also confers some regulatory powers on the Director and the Minister for the purposes of introduction of industrial chemicals (details are available in NICNAS's original submission to the PC study). Regulatory powers for down stream control of use reside with states/territories.

NICNAS notes the PC recommendation that the role of NICNAS should be limited to the scientific assessment of the hazards and risks of industrial chemicals (PC Recommendation 4.2). In order to ensure efficiency and effectiveness of the overall regulatory system for industrial chemicals, alternate processes for managing the regulatory functions currently undertaken by either the Director or the Minister (detailed below) require consideration if the proposed changes to NICNAS functions are adopted.

(a) New chemicals
Under the Act, the Director can issue permits authorising the introduction of new chemicals within specific conditions. The Director may also revoke new chemical permits under certain conditions. The PC recommendation as it stands would effectively remove NICNAS's ability to issue new chemical permits or revoke new chemical permits – both regulatory functions aimed at minimizing risks to human health and/or the environment.

Under the Act the Minister may authorise the introduction of a new chemical before assessment in the public interest within specific conditions. This regulatory power is intended to by-pass the new chemicals assessment process where a chemical is required in emergency situations.

(b) Conditions on introduction
Where the risk assessment demonstrates an overall risk to human health or the environment, NICNAS can establish conditions of use for the chemical through inclusion of those conditions on the Australian Inventory of Chemical Substances (AICS). Annotation does not constitute a ban on use rather it triggers re-assessment as a new chemical if it is to be used for the particular condition specified in the annotation.

Annotation of the AICS is within NICNAS powers and as such can be implemented concurrently with the issue of a new chemical certificate (for those chemicals that will be placed on the inventory immediately) or when the chemical is AICS listed after 5-years. For existing chemicals the AICS is annotated immediately following the assessment that

provides the basis of the annotation. Compliance with the condition of use can also be enforced by NICNAS under the Act. Use of the regulatory power to annotate the inventory ensures that there is no time lag between conclusion of the risk assessment and controls being legally enforceable, ensuring health and environmental protection. This is in contrast to using national standards or recommendation to state/territory regulators as the risk management mechanism (see details in section 3 below – Risk Management Standard setting and administration).

(c) Priority existing chemicals

Several tens of thousands of chemicals on the Australian inventory, ie existing chemicals, have not been assess for their health and environmental impacts. The Act provides a mechanism for review of existing chemicals on a priority basis, when health and environmental concerns are identified.

For Priority Existing Chemicals that are believed to pose an immediate unacceptable risk to human health and/or the environment, the Minister may ban/restrict use temporarily and pending the outcome of the NICNAS risk assessment. Given that full risk assessment on existing chemicals is labour intensive, this power is an important tool in managing high risk existing chemicals as an interim measure while they are subject to a comprehensive review.

(d) National standards for cosmetics

The Act enables the Minister, to make national standards in relation to cosmetics imported into or manufactured in Australia. These standards are applicable to cosmetic products and not individual ingredients. Penalties apply for con-compliance with these national standards.

NICNAS notes the PC recommendation to transfer responsibility for administrating and enforcing the Cosmetics Standard to the Australian Competition and Consumer Commission (ACCC) (PC Recommendation 5.6). The PC recommendation is interpreted to mean that NICNAS will continue to scientifically evaluate ingredients in cosmetics and list these chemicals on AICS under the Act. The ACCC will maintain and update the Cosmetic Standard and monitor compliance with conditions stipulated in the standard.

Further clarification is required on which elements of the Cosmetics Standard would transfer to ACCC and the mechanism by which assessment and regulatory functions will be linked. The Cosmetic Standard may need legislative amendment to better clarify NICNAS's scope, noting that there are some technical matters specified within the standard that require scientific verification to ensure compliance. Furthermore, scientific input may also be needed during the development of new standards.

(e) Post market feedback mechanisms

The Act establishes feedback mechanisms aimed at ensuring health safety and environmental outcomes through post market activities. For example, the Act requires introducers of industrial chemicals to notify significant changes in circumstances of the

use of an assessed chemical and any adverse health and environmental impacts (secondary notification). Where a new risk to public health or the environment from such post-market notification can reasonably be anticipated (ie additional to those identified in the original assessment) the Director may cause the chemical to be reassessed taking into account the changes circumstances.

Similarly the Director has the power to require annual reports on adverse effects and/or volumes for chemicals introduced under NICNAS exemptions, permits and self-assessments (these categories do not require full pre-market risk assessment by NICNAS). Some of these feedback mechanisms were introduced when introduction volumes that triggered pre-market assessment were increased, for example through Low Regulatory Concern Chemical Reforms. Removal of these information feedback mechanisms can potentially compromise human health or the environment.

All of the regulatory powers described above are aimed at ensuring the safe use of industrial chemicals and protecting human health and the environment. If the role of NICNAS were to be limited to the scientific assessment of the hazards and risks of industrial chemicals all of the regulatory powers outlined above would need to be considered and alternative mechanisms identified. In addition, clear and effective coordination between NICNAS and any other agency/body will be critical to ensuring an efficient, timely and effective regulatory system.

In contrast to the PC recommendation, the Review of the NICNAS Existing Chemicals Program sought to increase NICNAS's legislative powers to ban or restrict certain chemicals in order to control the use of certain high-risk chemicals. The proposal received mixed responses from industry, community and various levels of government. The proposal was deemed to be beyond the scope of the NICNAS Review and will be referred to the COAG Ministerial Taskforce on Chemicals and Plastics for consideration.

Governance structures

The Act does not provide for statutory mechanisms to advise the Director. Instead, NICNAS has established several non-statutory and informal mechanisms through which input is obtained from stakeholder groups. Three representative non-statutory bodies (the Community Engagement Forum, Industry Government Consultative Committee and the State/Territories Memorandum of Understanding group and one technical committee (Technical Advisory Group) provide advice on various aspects of the operation of the scheme.

The PC has recommended formalising and strengthening internal governance structures for NICNAS through establishing a statutory technical expert committee (PC Recommendation 4.3). This function is not covered under the Terms of Reference for NICNAS's existing representative advisory committees and the Technical Advisory Group, while expertise based, only provides technical advice on a specific NICNAS activity, namely confidential listing of chemicals on the AICS.

A statutory technical committee would establish a formal mechanism to obtain and bring together expert advice (as opposed to representational) on industry, community and

scientific issues relevant to chemical assessments. To ensure robust consideration of health and environmental protection, the technical committee would need to be independent and expert-based.

Unassessed industrial chemicals
The Report makes reference to the large number of unassessed existing industrial chemicals and notes the magnitude of the task if these were all to be assessed systematically. To address this concern, the PC recommends that NICNAS should implement a program to greatly accelerate the assessment of existing chemicals (PC Recommendation 4.4). NICNAS has policy approval to implement recommendations from the Review its Existing Chemicals Program to enhance regulatory efficiency and lead to more effective outcomes for the community, industry and government.

A key recommendation of the EC Review was to screen all AICS-listed chemicals in use in Australia for their risks to health, safety and the environment. Notwithstanding the budgetary impact of accelerating the assessment of existing chemicals (NICNAS is a fully cost-recovered scheme), there is already an agreed intent between Australia and Canada to explore collaboration regarding human health risk assessment and management of existing industrial chemicals. Considering the broader public interest to be addressed through an accelerated screening activity on existing chemicals, NICNAS is considering exploring the use of tools and other resources developed by Canada in undertaking a similar program. However, acceleration can only be achieved within budgetary constraints.

The PC has made observations on the feedback mechanisms for assessment activities. NICNAS has acknowledged the importance of post-market feedback mechanisms (including adverse experience reports) in order to identify existing chemicals of concern and refine and verify risk assessment conclusions. As distinct from therapeutics and pesticides, human and environmental experience data are rarely available for industrial chemicals, leading to greater uncertainty in the final risk characterisation. This issue is currently being addressed through NICNAS's EC Review, commencing with a scoping study to identify the key features of effective adverse experience schemes nationally and internationally.

Recognition of overseas assessment schemes
In the absence of an international standard setting body for industrial chemicals, NICNAS uses two strategies in its international harmonisation efforts; multilateral forums established by international organizations and bilateral arrangements with overseas regulatory agencies.

NICNAS notes the PC recommendation that it should urgently review the scope for recognising the assessment schemes of a range of other countries, with priority to be given to schemes operating in Canada, the EU and USA. The PC recommendation is made in the context of accelerating NICNAS's assessment of existing chemicals.

The Act makes provisions for recognition of approved foreign schemes for new industrial chemicals (only). NICNAS has already approved the Canadian New Substances Program as an approved foreign scheme and collaborative activities are underway, including NICNAS acceptance of Canadian hazard assessment and providing a 40% fee rebate. No reciprocal provisions are available in the Canadian industrial chemicals regulations.

Although the Act does not extend approved foreign scheme provisions to existing chemicals, the Australian and Canadian Governments have formally declared their intent to explore collaboration regarding human health risk assessment and management of existing industrial chemicals. NICNAS is currently working with Health Canada and Environment Canada to progress this agreement. As a first step NICNAS will explore the utilisation of tools and resources developed by Canada in undertaking screening of their national chemicals inventory.

NICNAS is collaborating with the US EPA via the OECD New Chemicals Taskforce activity on the Mutual Acceptance of Notification Parallel Process. NICNAS has also commenced bilateral discussion with the EPA with a view towards further collaboration on assessment related activities.

NICNAS and the New Zealand Environmental Risk Management Authority (ERMA) have a Memorandum of Understanding (MoU) that establishes a co-operative relationship between the parties in connection with industrial chemicals which may also be hazardous substances. In addition, the ongoing Trans-Tasman Mutual Recognition Arrangement between Australia and New Zealand includes a 5-year work plan to determine a final position for industrial chemicals that are currently subject to an annual special exemption from mutual recognition. Further details on the work plan are provided in Attachment 1.

Low Regulatory Concern Chemicals (LRCC)
Consistent with its commitment to continuous improvement, NICNAS worked closely with all stakeholders to develop a greater range of options for industry, through the LRCC reforms. These reforms introduced flexibility into the assessment process to enable the fast tracking of low regulatory concern chemicals while maintaining existing levels of worker safety, public health and environmental standards. The reforms also sought to ensure the regulatory effort expended by NICNAS and industry was commensurate with the risk posed by these chemicals. NICNAS is currently drafting the final raft of regulations to give effect to remaining LRCC categories and complete this reform activity.

Feedback from industry indicates that while some LRCC reforms have provided significant benefits to industry, other reforms have proved difficult to utilise. NICNAS will shortly commence an evaluation of the LRCC reforms that have already been implemented to ascertain their effectiveness and identify opportunities to assist industry use of low concern/low cost categories introduced under this activity.

Chemicals in articles
Under the Act, articles are exempt from the scheme. Therefore, while NICNAS has the power to assess chemicals released from articles, it cannot assess articles themselves. The ACCC has overall policy responsibility for monitoring the conduct and outcomes of consumer goods safety.

The PC has recommended that there is scope to strengthen cooperation between NICNAS and the ACCC on chemicals in articles through formal institutional links (PC Recommendation 5.5). While NICNAS and the ACCC have informal linkages, the need for more effective communication and coordination of efforts has been demonstrated in recent times. A more formalised arrangement between NICNAS and the ACCC will provide overall benefits through ensuring a more systematic, coordinated and proactive approach to the management of chemicals in articles.

3. Risk management - standard setting and administration

The NICNAS risk assessment identifies the risks posed by the chemical for its intended (for new chemicals) or known uses (for existing chemicals) over its full life cycle. Where necessary, the risk assessment recommends risk mitigation measures, either through national standards or other controls. Recommendations for national standards are directed at standard setting bodies, and other controls are directed at state/territory agencies and industry. Ultimately it is the relevant state/territory agencies that give legal force to all NICNAS recommendations except those directed at industry, by adopting national standards or adopting the recommendations directly.

To facilitate nationally consistent application of standards across the various states/territories, NICNAS utilizes national frameworks in drafting OHS and public health recommendations. OHS recommendations are framed in accordance with National Model Regulations for the Control of Hazardous Substances in the Workplace and the National Dangerous Goods Framework. Similarly, NICNAS's public health recommendations are framed in accordance with the National Drugs and Poisons Schedule Committee (NDPSC) guidelines, for inclusion in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Where public health and/or OHS controls are deemed necessary, the NICNAS assessment report is forwarded to the relevant standard-setting body for consideration; the NDPSC for public health or the Office of the Australian Safety and Compensation Council (OASCC) for OHS.

The lack of a nationally agreed environmental risk management framework adversely impacts on the framing and uptake of NICNAS's environmental recommendations by state/territory regulators. The Environment Risk Management Framework for Chemicals (NChEM) is proposing reforms to improve the environmental management of chemicals through a range of proposals.

For new chemicals NICNAS issues certificates and permits that enables their introduction/commercialization. As part of the new chemical assessment process, workplace classification and labeling is recommended, where appropriate. There is an expectation, but

no legal obligation, for NICNAS recommendations on classification and labeling to be picked up. As part of the new chemical assessment, NICNAS also examines the information provided to workers (and in some instances consumers) through the Material Safety Data Sheet (MSDS) for the chemical and makes recommendations for its revision, where required to protect human health and the environment.

There is no legal requirement either for standard setting-bodies to consider NICNAS's recommendations nor for states/territories to adopt national standards or direct recommendations before NICNAS permits/certificates are issued. For both new and existing chemicals this can result in a situation where a chemical that NICNAS consider to warrant risk management measures, is on the market without controls in place and without any statutory or binding agreement on the timeframe within which such controls should be considered/adopted.

In 2007-08, NICNAS undertook an evaluation of the *Uptake of NICNAS's Recommendations by Government Chemical Management Bodies.* Key findings from this evaluation and the way forward are detailed in Attachment 2.

The delay in uptake of NICNAS recommendations was an issue identified through the NICNAS EC Review. The Review found that a rigorous investigation of the complex and multi-layered regulatory arrangements is needed to identify the underlying barriers to achieve a streamlined and harmonised uptake of recommendations by all parties. Given their broader policy implications, the review concluded that the matter was beyond its scope and recommended that barriers to the effective implementation of NICNAS's recommendations in a streamlined and harmonised manner be referred to the COAG Ministerial Taskforce on Chemicals and Plastics for consideration.

NICNAS notes the PC recommendation to establish expert based independent standard setting bodies for each of the three sectors supported by appropriate intergovernmental agreements. For NICNAS recommendations to be effectively linked into the Commonwealth's risk management framework, it will be necessary to strengthen and formalise the linkages between NICNAS and national coordinating bodies. .

Strengthening linkages with state/territory agencies
NICNAS has a formal relationship with states/territories through the NICNAS States/Territories Memorandum of Understanding Group.

NICNAS notes the PC's support for strengthening linkages and broadening state/territory consultation to include public health and environmental agencies. NICNAS is presently engaging in active dialogue with agencies representing to all three sectors, (OHS, public health and environment) with a view to enhancing the efficiency and effectiveness of the States/Territories MoU. This activity was commenced as part of the implementation of outcomes from NICNAS's Existing Chemicals Review.

CONCLUSION

NICNAS notes the suite of recommendations arising from the draft PC Research Report that has its primary objective the assessment of the efficiency and effectiveness of current institutional and regulatory frameworks.

Several PC recommendations and observations are consistent with outcomes from NICNAS's Review of its Existing Chemicals Program. As such some PC recommendations are under active consideration already at NICNAS under a program of work to implement the outcomes from the EC Review. Additionally, some planned evaluations of recent reforms such as the LRCC reforms also address concerns raised in the PC study.

Other PC recommendations require further clarification of intent and consideration of implications in order to ensure a seamless interface between NICNAS and risk management agencies/bodies. The efficiency and effectiveness of the current regulatory framework can be improved by formal links/agreements between risk assessors, risk managers with attendant matters such as timely consideration of risk assessment outcomes built into formal agreements.