ENVIRONMENT PROTECTION AND HERITAGE STANDING COMMITTEE SUBMISSION

in response to the

DRAFT REPORT OF THE PRODUCTIVITY COMMISSION STUDY INTO CHEMICALS AND PLASTICS REGULATION

Summary

The Productivity Commission's Draft Report contains a wide ranging series of proposed reforms to improve the efficiency and effectiveness of, and streamline, the current chemicals regulatory regime in Australia and the Commission is commended for producing such a clear and comprehensive Draft Report on what is a highly complex set of issues.

The Commission has recognised that "the regulatory framework for managing the impact of chemicals on the environment could be improved"[1]. The Commission's support for the *National framework for Chemicals Environmental Management* (NChEM) is also noted.

The following proposals are supported:

- The proposed cross-Ministerial Council chemicals standing committee, *pending further refinement of the details of its operation and location as outlined below*.
- Acceleration of the risk assessment of 'existing' chemicals.
- Formalised environmental regulatory arrangements, noting that the NChEM Working Group would be happy to explore model options, details and mechanisms further with the Commission.
- Improved information feedback mechanisms and environmental monitoring initiatives.
- A formalised approach for the risk management of chemicals in consumer articles that establishes clear roles and responsibilities, *noting however that the environmental components need to be addressed as well as public health and safety*.

A number of the Commission's proposed reforms could benefit from further elucidation. Clarification/further work is needed on the following issues:

- The apparent differences between the proposed roles for the APVMA and NICNAS.
- The role/place of 'risk assessment' and 'risk management' functions within the proposed governance framework, including practical level application detail.
- The proposed environmental regulatory model, in particular details on the operation and role of the environmental standard setting body.
- The proposed place of cost benefit analysis within the chemical assessment and risk management regime, noting that the wide application of cost benefit analysis requirements to *all* chemical assessments, as appears to be suggested in the draft report, would not be supported.

More detailed comments follow.

[1] Productivity Commission 2008, *Chemicals and Plastics Regulation*, Draft Research Report, Canberra, p193.

Comments on Draft Report and recommendations

Environment agencies have been pleased to have the opportunity to engage with the Productivity Commission during the course of this Study. The Commission's Draft Report contains a series of proposed reforms, of which Draft Recommendation 8.1 and the supporting discussion in Chapter 8 are of particular relevance to environment agencies. However, many other proposals relating to chemical risk assessment and management frameworks and broader governance reforms are also of interest. Key recommendations are discussed below.

The Commission is to be commended for acknowledging that the current chemicals regulatory regime is "less effective at managing risks to the environment" than in delivering other outcomes[2] and that government action may be warranted to manage the environmental impacts of chemicals, and for proposing a package of reforms to improve efficiency and effectiveness in this area.

NChEM was endorsed by Environment Ministers in June 2007 and is currently being implemented with stakeholder support. NChEM is already delivering improvements in chemicals environmental management. The Draft Report is broadly supportive of the NChEM framework in working to resolve the issues identified in the area of environmental management of chemicals. The Commission recognises that "it is expected that the reforms being progressed will improve effectiveness and efficiency, and there is early indication that some parts of NChEM are producing positive outcomes"[3], for example in the area of environmental risk assessments. NChEM is consistent with the Commission's proposed reforms and the EPHC's NChEM Working Group commits to working with the Commission to finalise and clarify the detail of its Report and to the ongoing COAG reform processes.

Key areas for further consideration/clarification

MODELS FOR ENVIRONMENTAL RISK MANAGEMENT

Both NChEM and the Commission's Draft Report propose that chemical environmental management outcomes can be improved by establishing a new mechanism to coordinate and implement industrial chemical risk assessment report outcomes relating to the environment. NChEM had proposed to place such a mechanism within existing systems and structures (i.e. by centralising roles into a single chemical assessment and risk management agency comparable to the agvet chemical model). On the other hand, the Commission's Draft Report proposes an environmental regulatory model centred on the creation of a new environmental standard setting body to take on the role of risk management advisor and coordinator. Both models agree that decisions on hazard and risk assessment and risk management should be taken nationally and adopted consistently in all jurisdictions.

The NChEM Working Group would welcome the opportunity to discuss and further explore the details of the Commission's environmental regulatory model, given our mutual interest in designing an efficient and effective model.

In this regard, while recognising that the Commission's proposed model is capable of delivering the environmental solutions necessary for a well functioning chemicals management system, a number of aspects of the model are not clear in the Draft Report. In particular:

- What is the proposed nature/composition of the environmental standard setting body? What does "constituted to reflect the broader public interest" mean practically?
- What is the role envisaged for government in decision-making on chemical environmental risk management as compared to the role of the independent standard

[2] Ibid, Overview: pxxv.
[3] Ibid, p217.

setting body of external 'experts'? What additional advisory bodies[4] would the standard setting body be expected to draw on (given this body is itself envisaged as an independent body constituted in the "broader public interest" and acting as an advisory body to government)? We understand from discussion with the Commission that the EPHC is intended to be the ultimate decision-maker, however the Draft Report suggests the standard setting body may be empowered to make decisions on national environmental standards *necessarily involving changes to legislation* and *draft regulations* intended to be subsequently *automatically* adopted in jurisdictions[5]. The role of the EPHC in this process is not explicitly stated.

- Whether the standard setting body would handle all chemicals or only industrial chemical risk management issues?
- What is the Commission's understanding of 'standards'? Would the standard setting body handle regulatory responses for management/regulation of both 'low risk' chemicals and 'high risk' chemicals?
- Questions of funding arrangements for any new environmental standard setting body would require careful consideration once the nature and operation of such a body was agreed (noting the contrast between existing APVMA cost recovery arrangements and the Commission's proposed jurisdictional cost-sharing model is not clearly explained).
- What would be the status of NICNAS's, or other, inputs to the body? For example, would the standard setting body be *required* to consider or act on (either all or some of) NICNAS assessment reports? What other inputs/sources are anticipated?
- Would the standard setting body also have a proactive and strategic role, in addition to considering NICNAS assessment reports, for example could the body initiate a new standard or priority existing chemical review process?
- What is the proposed delineation of roles between NICNAS and the standard setting body, noting that risk assessment and management are a linked iterative process?
- How does the Commission envisage drawing on the National Transport Commission model for the operation of the standard setting body? More detailed explanation of the application of this model to chemicals environmental management would be helpful.
- Would regulatory impact analysis be required for *all* environmental controls as suggested[6] or only where there is likely to be a *significant* impact on business?

The NChEM Working Group would be happy to participate in a workshop with the Commission to discuss models and mechanisms. The Working Group believes that any model for environmental management of chemicals needs to be built around:

- a simple, efficient and strong national mechanism;
- resource efficiency and effectiveness (both in its establishment and ongoing operation);
- timeliness of decision-making;
- avoidance of duplication - in consideration of chemical risks and management actions;
- integration with the full range of risk management considerations (i.e. to avoid decision-making in isolation from other pertinent factors such as public health requirements or industry needs); and
- the most sensible and effective allocation of regulatory powers (e.g. where should the power to ban a high risk chemical reside?).

[4] Ibid, p222.
[5] Ibid, pp221-222.
[6] Ibid, p222.

NChEM

- The Report states that the Environment Protection and Heritage Council (EPHC) "should continue to assess the need for a national framework for the management of chemicals in the environment"[7]. The EPHC has already assessed the need for, and has endorsed, a national framework and an NChEM Action Plan which is currently being implemented. Environment Ministers agreed to undertake further assessment of possible regulatory reform in chemicals environmental management taking into account the Commission's Study and COAG Ministerial Taskforce outcomes. The NChEM Working Group would be happy to participate in further discussions.
- The Commission questions whether NChEM's preferred regulatory model would replace existing state/territory legislation, and is concerned that "if not, it could become an additional layer of regulation"[8]. To clarify: NChEM's model aims to use/ amend existing legislative frameworks (i.e. NICNAS's legislation and generic existing state/territory environment protection legislation), not add new regulations.
- The Commission also raises a concern that "*unless appropriately constrained*, the [NChEM preferred regulatory model] could leave the way open for individual states and territories to amend the proposed arrangements…"[9]. NChEM's proposed model consists of automatic, consistent adoption of NICNAS environmental risk assessment outcomes, with only very limited provision for opt-out under exceptional circumstances. This reduces the likelihood of variation between jurisdictions.
- The Commission acknowledges that "some additional monitoring of the impact of chemicals on the environment may be required"[10]. There is indeed a critical need for additional environmental monitoring of chemicals. This has been starkly highlighted by recent research findings of elevated levels of brominated flame retardants in wildlife. The EPHC has agreed on the need for more environmental monitoring and endorsed the implementation of monitoring initiatives by the NChEM Working Group.

NATIONAL POLICY AND SYSTEM GOVERNANCE

A cross-Ministerial Council chemicals standing committee

- The proposal to establish a national cross-Ministerial Council chemicals standing committee (Draft Recommendation 3.1) broadly responds to the EPHSC submission's call for a mechanism for national chemicals policy coordination and communication. We welcome an integrated body, inclusive of environmental views, that is appropriately resourced. The EPHSC would like to be further involved in discussing questions of operation, membership, reporting structures and responsibilities.

National regulatory agency roles

- There is an apparent disparity in the proposed responsibilities and powers between the APVMA (whose role covers risk assessment and risk management/standard setting functions and would be expanded further to cover 'control-of-use') and NICNAS (whose powers would be pared back and whose role would cover risk assessment only) under the Commission's proposed new framework. The responsibilities of the APVMA do not appear to align with the four tier governance model (i.e. it would apparently cover both levels two and three). Further elaboration of the proposed operations of the agvet versus industrial chemicals models is required.

NATIONAL HAZARD AND RISK ASSESSMENT

Further clarification is required on how the Commission envisages implementation of its reforms to risk assessment processes and the operation of NICNAS and the APVMA, in particular with regard to Draft Recommendations 4.1, 4.2, 4.4 and 4.5 as outlined below.

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[7] Ibid, p223.
[8] Ibid, p219-220.
[9] Ibid, 219.
[10] Ibid, p193.

Cost benefit analysis driver in NICNAS and APVMA risk assessment processes

- The Report lacks detail on the implications of the proposed introduction of a cost benefit analysis (CBA) driver in APVMA and NICNAS assessment processes (Draft Recommendations 4.1 and 4.5), including:
    - At what point in the risk assessment process would a CBA be undertaken?
    - When would the CBA requirement apply/be triggered? *(Noting NChEM stakeholders agreed such a requirement should only apply to significant outcomes such as bans/phase-outs and that if such a requirement were applied broadly it would impact on the timeliness of risk assessments).*
    - How the proposed purely scientific assessment role of NICNAS fits with the proposed introduction of a NICNAS CBA function (i.e. a policy - and arguably risk management - function).

Risk assessment versus risk management

- It is important that the integrity of the risk management process is maintained, regardless of the governance framework or regulatory model ultimately adopted for chemicals management. Further clarification on how this would be achieved under the Commission's draft proposals would be helpful. In particular:
    - What is meant by proposals to separate the 'risk assessment' and 'risk management' parts of chemical assessments?
    - How would these functions be divided between relevant institutions/bodies? (e.g. would an industrial chemical assessment agency make risk management *recommendations* as part of its assessment process?
    - How would the integrated and iterative functions/processes of risk management and assessment be accommodated?
    - How would best practice be operationalised, noting the internationally and nationally accepted and effective risk management standards[11]?

Accelerating the assessment of existing chemicals

- Draft Recommendation 4.4 addresses a key concern raised in the EPHSC submission and is supported. New resourcing to assist in the acceleration is also supported, given that there is not a simple solution to this challenge.
- Increasing the use of overseas data or risk assessments where feasible and valid is also supported, including maximising the use of the data contained within overseas assessment reports and approaches such as scanning overseas risk assessments to determine their applicability to the Australian context. It should be acknowledged that Australian specific data will still be required where chemical use patterns in Australia differ from those overseas and where Australian receiving environments are different.
- Further discussion of the constraints on the use of tools such as modelling, overseas assessments and screening/prioritisation tools is provided in **Attachment B**.

Industrial chemicals regulatory reform proposals

- The Commission proposes to remove from NICNAS the power to annotate the *Australian Inventory of Chemical Substances* (AICS). AICS has significant potential as a useful information tool enabling information on a chemical to be centrally located and accessible (e.g. for recording secondary notification requirements, information on restrictions etc.). An alternative tool should be proposed if AICS powers are to be removed from NICNAS. It is not clear where current NICNAS regulatory powers will reside if such powers are removed from NICNAS (e.g. control of use powers relating

[11] In this regard 'risk management' is usually defined as the overarching process that includes risk assessment, risk mitigation, risk communication and risk identification. For example, Standards Australia has developed a risk management standard (AS/NZS 4360:2004) which, in line with other overseas standards, defines risk management as the whole process of looking at risk. It starts with the identification of risks, moves through risk assessment and includes decision-making, risk mitigation and monitoring. **Attachment A** provides additional comment on the difficulties of fully separating risk assessment and management functions for chemicals.

to AICS such as setting import volume limits). Further elaboration in the Final Report would be useful.

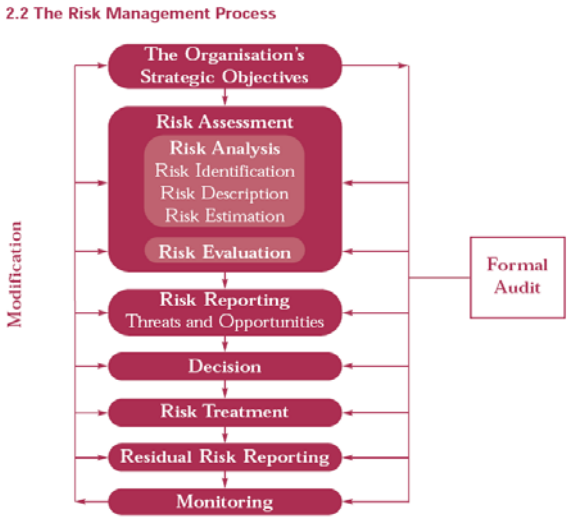
PUBLIC HEALTH

Proposed arrangements to address chemicals in consumer articles

- A number of the Commission's recommendations refer to the Australian Competition and Consumer Commission (ACCC), yet the ACCC is not included in Table 1 of the Draft Report. It would be helpful to show how the ACCC would fit into the overall regulatory system under the Commission's preferred institutional arrangements, and provide more detail on the proposed role of the ACCC for managing chemicals in consumer articles.
- The Commission's proposals for the establishment of arrangements between the ACCC and NICNAS to address the issue of chemicals in consumer articles (Draft Recommendations 5.4 and 5.5) are strongly supported.
- However, it is noted that the proposal currently omits discussion of the *environmental* component of the risks and impacts of chemicals in consumer articles. This is an important part of the current regulatory gap in managing chemicals in consumer articles noting the potential for chronic/long-term environmental impacts, particularly from release of persistent chemicals (including those capable of long range transport) from articles in use. The Commission is referred, for example, to the recent scientific research findings of brominated flame retardants in wildlife (e.g. Tasmanian Devils) in locations where they have never been used or manufactured.
- In addition the question of where strategic, pro-active policy and decision-making responsibility for chemicals in consumer articles will reside is not clear.

Risk assessment versus risk management

Risk management is usually defined as the overarching process that includes risk assessment, risk mitigation, risk communication and risk identification. Standards Australia has developed a risk management standard (AS/NZS 4360:2004) and, in line with other overseas standards, this defines risk management as the whole process of looking at risk. It starts with the identification of risks, moves through risk assessment and includes decision-making, risk mitigation and monitoring. This integrated process is well demonstrated by the diagram below, which comes from a United Kingdom risk management standard and is similar to the process contained in the Australian Standard[12].



An important aspect of chemical risk assessments is their dependence on the assumptions made for the parameters which are variable or where there are not significant scientific data available to support them. While these assumptions are based on expert scientific judgement and extrapolations from the best available data, they nevertheless represent a source of uncertainty that must be taken account in decisions/interpretations about risk. The type of assessments undertaken by NICNAS and APVMA therefore take a standardised approach to these parameters, which means the assessments are comparable between chemicals but it does not mean that the *real* risk (or the complete set of risks) has been able to be quantified with complete scientific certainty. A key risk management decision-making aspect of the process is then reflected in the fact that, once the risks have been initially estimated, an iterative process begins to include risk mitigation measures until the risks fall into an acceptable category (if the initial assessment shows risks to be in the unacceptable category).

Consideration of 'risk management' in the context of the Commission's Report is, in fact, a critical component of a typical 'risk assessment' undertaken by NICNAS or the APVMA. This is especially pertinent for the environmental component: the context in which environmental assessments are undertaken limits the amount of standardisation that can take place because many environmental protection decisions must be made on a case-by-case basis due to the limited theoretical understanding of the systems we are trying to protect, which limits our ability to design appropriate assessment systems (consequently the systems we design are based on conservative assumptions). Some of the limitations include:

- Humans have irreversibly altered many 'natural ecosystems'.
- Protecting ecosystems in these altered areas may be of little importance while protecting those few remaining areas (depending on the type of ecosystem) of some natural ecosystems may require significant efforts to be really confident

[12] Taken from page 6 of http://www.theirm.org/publications/documents/Risk_Management_Standard_030820.pdf

- Ecosystems that are altered still need to function in a healthy way to support both humans and other/remaining organisms – the level of protection required for such areas depends on the level of alteration and the level of resilience of the system.
- Ecosystems are extremely complex and there is only a limited understanding of what the critical components are, so it is not clear whether the organisms currently being used in ecotoxicity tests are the best indicators of environmental impact. In fact ecotoxicity testing methodologies are only available for those organisms that can be readily used in laboratory studies. This is likely to skew our final picture of environmental impact.
- We do not know how much damage can be sustained by an ecosystem, yet still allow for it to recover or continue to function in a healthy way. But we do know that it varies depending on the type of ecosystem.
- Environmental monitoring has focused to date on a very limited set of chemicals – those which people had identified as a problem – so the development of guidelines and research into effects is biased toward this limited set of chemicals.
- When looking specifically at synthetic chemicals it is important to recognise, for example, that:
    - there is currently no formal process for checking what synthetic chemicals are entering the environment or at what concentrations;
    - persistent chemicals can move long distances into remote areas of the planet and there is no process for evaluating intergenerational and cross-border impacts;
    - chemicals used as human therapeutics or in foods are presumed not to reach the environment and so their use for these purposes is not currently assessed for environmental impact in Australia, and yet available studies clearly indicate such chemicals are actually reaching the environment, in some cases in high concentrations (this may or may not be a problem – but we do not *know*); and
    - analytical procedures for many older chemicals do not even exist.

  As a result, environmental assessments of synthetic chemicals must err on the conservative side because there is so much that is not known and significant variation depending on where the chemical might be used.

It should be noted that public health and occupational assessments suffer from similar types of limitations even though we know much more about how the human body works and how some chemicals interact with systems in the body.

The so-called 'risk averse' nature of NICNAS and the APVMA can actually be interpreted as an indication of their expert understanding of the limitations of the risk assessment/ management process. Clearly, in any chemicals assessment/management system there needs to be a balance between asking for data on chemicals and recognising the costs of obtaining such data, in how conservative an approach is adopted, and in taking into account what risk management options are available. The system also needs to be reviewed regularly to ensure that it remains appropriate as our understanding improves. In relation to this issue the EPHSC supports the Commission's acknowledgement that "post-market feedback mechanisms can be useful for verifying risk assessment conclusions"[13] would like to reiterate the need for appropriate mechanisms to be built into the chemicals regulatory system. EPHSC is also of the view that the assertion that Australian regulators are 'risk averse' needs to be more critically examined. Evidence, preferably quantitative evidence, should be provided to support the claim. The Commission may wish, for example, to compare the risk management decisions by Australian regulators with the decisions for the same chemicals by overseas regulators to see if there is any pattern of "risk averse" behaviour by Australian regulators.

[13] Productivity Commission 2008, p60.

ATTACHMENT B

Tools for accelerating the assessment of 'existing' chemicals

There is not a simple solution to the challenge of accelerating the substantial backlog of unassessed 'existing' industrial chemicals. Even with the introduction of measures proposed by the Commission, there are considerable challenges. Some of these are discussed below.

Screening and prioritisation initiatives

Canada recently undertook a comprehensive categorisation process for all of its 'existing' chemicals - approximately 23,000 chemicals on its Domestic Substances List. To screen and prioritise chemicals, Canada used indicators of persistence, bioaccumulation, inherent toxicity and human exposure to screen their database of existing chemicals. This is the only efficient way to undertake such a task. The important aspect of this process is the use of actual data for the different characteristics wherever possible in order to minimise false positives (i.e. chemicals registering as a concern when they really are not). Where actual data are not available, use of models to estimate the result for a chemical is feasible. However, typically these models are (and need to be) designed to estimate the parameter values in a conservative fashion because the principal goal of the screening system should always be to eliminate the risk of false negatives (i.e. chemicals being classed as no concern when they actually are of concern). Applying such parameters to the screening process leads to a list that is slightly longer than it needs to be because it will inevitably contain some false positives, however this is a much more desirable outcome than having potentially high risk false negatives in the initial screening list.

Modelling

Similarly use of modelling in place of actual data has some limitations and should be used with care. It is important to ensure local applicability and consider the validity of assumptions and data upon which the model design is based. For example Quantitative Structure-Activity Relationships (QSARs) use chemical analogue behaviour/relationship trends to estimate the toxicity of a chemical. This is a valid approach if the dataset used to develop the trend curve is sufficiently large, the indicator of similarity is useful/relevant (i.e. the indicator of similarity used truly reflects similar behaviour/toxicity between the chemical and its analogue. If the relationships are somewhat tenuous because the data set is small or the chemicals are not really very similar then the models will not produce very reliable outcomes. For example the NChEM Working Group is aware of a case, where the QSAR outcome for a flocculant said a product had a toxicity of 280mg/L but when actually tested to confirm this, it was found to have a toxicity of <7mg/L which is much worse and significantly changes the response. This example also demonstrates the potential difficulties of attempting to choose behavioural analogues for *polymers*.

It should also be noted that standard QSARs are available for download free of charge from the USEPA and, indeed, the Commonwealth Department of the Environment, Water, Heritage and the Arts (DEWHA) currently uses QSARs in its environmental risk assessments, when appropriate, so "currently unavailable in Australia"[14] may be misleading.

Use of overseas data or risk assessments

In many cases it is not valid to simply adopt overseas risk assessments. There should be acknowledgement of the limitations of recognising overseas assessments and careful consideration of when this approach would be applied. Given Australia undertakes risk assessments (not hazard assessments), directly adopting reviews by other countries in their entirety is not feasible because the risk depends on how it is used here. However, it *is* valid to make the maximum use of the data contained within overseas assessment reports. It would also be possible to implement a process whereby overseas risk assessments were scanned to determine their applicability to the Australian context (i.e. and then not repeat assessments where they were found to be truly reflective of Australian usage patterns and receiving environments).

[14] Ibid, p56.