Australian Government
Department of the Environment and Water Resources

Submission to the Productivity Commission Study into Chemicals and Plastics Regulation

Department of the Environment and Water Resources

October 2007

GPO Box 787 Canberra ACT 2601 Telephone 02 6274 1111 Facsimile 02 6274 1666
www.environment.gov.au

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Executive Summary

On the basis of our broad involvement with international chemical regulators and standards, the Department considers that the current regulatory system for managing chemicals in Australia is of a high standard and compares favourably with other OECD countries in most respects. However, there are a number of challenges and constraints that prevent Australia from meeting current international best practice for whole of life chemicals management, particularly, from our perspective, in relation to protection of the environment and human health from the impacts of chemicals.

Public confidence in the use of chemicals in Australia relies on people having trust that a regulatory system is in place which deals effectively with all aspects of chemicals management from assessment through to use and disposal. There are tangible opportunities for improving the way chemicals are managed in Australia. Some of these opportunities could be realised through incremental change; others may require more significant changes to the existing regulatory system.

Incremental changes of benefit for environmental protection, for industry and for users, and which would lead to increased public confidence, include:

i. improving access to better information for hazard and risk assessments so that the behaviour of chemicals in the receiving environment can be more accurately predicted, leading to better targeted risk management measures which are neither insufficiently protective nor unnecessarily restrictive. This will also reduce duplication of data requirements and accelerate assessment of new and existing chemicals;

ii. improving the monitoring of chemical behaviour in the environment so that potential problems can be identified early, the accuracy of initial hazard and risk assessments can be tested and refined, the appropriateness of risk management measures can be reviewed, and remedial measures can be identified and implemented in a timely fashion where necessary;

iii. implementing the Chemicals Action Plan for the Environment as endorsed by the Environment Protection and Heritage Council (EPHC);

iv. confirming the role of this Department in the provision of advice on the environmental impacts of chemicals.

Several industry groups have called for the development of a national chemicals policy as a basis for delivering major changes to the existing regulatory system (for example, the Chemical and Plastics Industry Key Action Agenda). The absence of a national policy has been cited as contributing to a situation in Australia in which, as the Commission has noted in the Issues Paper, fundamental reform has been difficult to achieve.

A national chemicals management policy could provide the guiding structure for achieving simplification and streamlining of the current regulatory system, which some perceive as complex and fragmented, and for addressing existing gaps and deficiencies.

It should not be assumed, however, that developing a national policy would necessarily lead to significant structural change. It may confirm that the existing structures and institutions provide an appropriate foundation for building a more effective system. Significant benefits would need to be demonstrated to justify the cost and inconvenience of embarking on major structural change.

The Department suggests that worthwhile incremental improvements within the current regulatory system could be pursued in parallel with a structured process overseen by the COAG Task Force bringing together all relevant stakeholders to see whether there is scope for an improved overall model for chemicals management. This model would need to encompass appropriate recognition of the full spectrum of chemical issues from international agreements on chemicals to the safe use and disposal of toxic chemicals within Australia, and the resourcing required to effectively manage risks for long term sustainability. Ideally, this would result in a national chemicals policy, setting out clearly defined outcomes, outputs, functions and roles for all levels of government and the private sector.

Introduction

The Department of the Environment and Water Resources (DEW) welcomes the Productivity Commission's study into the regulation of the chemicals and plastics industries in Australia. The Department is keen to see an appropriate, efficient and effective regulatory system in place that improves operational conditions for industry by reducing costs and red tape, while ensuring that risks to the environment and human health are properly assessed and minimised.

The Department considers that the current regulatory system for managing chemicals in Australia is of a high standard and compares favourably with other OECD countries in many respects. Nonetheless, it also sees opportunity for improvement. Some tangible improvements could be realised through incremental change, other possible improvements may require significant changes to the existing regulatory system.

If the path of major change is to be pursued, the Department believes that it should be done within a comprehensive context, such as development of a national policy for chemicals management. Australia lacks such a national policy, in comparison with major OECD countries which have invested significant effort in developing and designing cohesive and encompassing systems to manage chemicals (refer Appendix 1). The absence of an overarching framework can lead to perceptions that regulation is being pursued as an activity in itself, rather than as an important and integrated element within a national policy for chemicals management.

A national policy should have clearly defined outcomes, outputs, functions and roles, as well as quantifying costs and benefits. From an environmental perspective, a national policy would need to cover the full perspective of chemicals management from international agreements on the use of chemicals, to the safe disposal of toxic chemicals within Australia. It would address public and private sector responsibilities and related financial and economic issues.

The Department notes that industry groups also have called for the development of a National Chemicals Policy, including a nationally consistent mutual commitment to:

1. environmental quality
2. workplace and consumer health and safety
3. an internationally competitive chemicals industry
4. consumer education.

The unifying structure of a national policy may be the most effective context for achieving simplification and streamlining of the current system, which some perceive as complex and fragmented, and for addressing existing gaps and deficiencies. It should not be assumed, however, that developing a national policy would necessarily lead to significant structural change. It may confirm that the existing structures and institutions provide an appropriate foundation for building a more effective system.

It is worth noting that it would be possible to pursue "no regrets" incremental improvements in parallel with development of a national policy.

In this submission, the Department attempts to identify, from its perspective of seeking to ensure the safe management of chemicals in the environment, the changes that could be

realised through incremental action, as well as those which would require major review. It canvasses some of the broad benefits and disadvantages of the proposed changes but, at this stage, without detailed costings.

The submission is structured in three parts:

- A description of the Department's current role in chemicals management, which will help to provide context for its comments.
- A comparison of Australia's chemical management with the approach taken by other OECD countries.
- Options for improvement in the short, medium and long term.

The current role of the Department

The Department has several distinct roles in chemicals management within Australia, none of them as a statutory regulator within the context of the current Productivity Commission study.

The Department is, however, the national statutory regulator for chemicals which are ozone depleting substances and for synthetic greenhouse gases through its administration of the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989* and for the import and export of hazardous waste, including chemicals, under the *Hazardous Waste (Regulation of Exports and Imports) Act 1989*.

i. International Agreements

The Department has lead responsibility, and is delegation leader, for the international chemicals conventions and agreements which Australia has ratified or otherwise endorsed. These include the UNEP family of agreements: the Stockholm Convention on Persistent Organic Pollutants, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and the Strategic Approach to International Chemicals Management (SAICM). It also includes the OECD Control of Chemicals Programme headed by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides, and Biotechnology (the "Joint Meeting"), which runs under the OECD's environment portfolio.

The Department also has responsibility for the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and for the Montreal Protocol on Substances that Deplete the Ozone Layer, which have additional implications for chemicals management.

The Department notes that there has been exemplary cooperation amongst Commonwealth, State and Territory agencies, industry, scientific and community groups in reaching an agreed Australian position for each of these international forums and in relation to participation by these groups in Australian delegations.

This high level of cooperation has been facilitated by:

- a genuine mutual commitment to cooperation, discussion and sharing of information in forming Australia's position;
- a shared understanding that public confidence in the use of chemicals in Australia requires public confidence in the regulatory system;

- acceptance that chemicals regulation in Australia is based on identification of hazards and implementation of appropriate risk management procedures;
- agreement that both international and domestic actions concerning the use of chemicals should be based on the best available scientific evidence.

Ratification of legally binding international agreements on chemicals entails a responsibility for ensuring the proper management of those chemicals within Australia. Ratifications for existing agreements have proceeded on the basis of agreement from State and Territory governments that much of this management would be done under existing State and Territory legislation. Ultimately, however, the responsibility to ensure that Australia's obligations under these international agreements are being met lies with the Australian Government.

ii. National chemical policies

The Department has taken the lead or been instrumental in developing a number of national policies on specific chemicals or groups of chemicals. Most of these have been either in anticipation of or in response to requirements arising through Australia's participation in legally binding international agreements. Examples are:

- Australian National Implementation Plan (NIP) for the Stockholm Convention on Persistent Organic Pollutants – the NIP was finalised in July 2006, and outlines actions Australia had already taken up to that point in implementing the requirements of the Convention, and further actions proposed to be undertaken to meet Convention obligations. The NIP was developed in consultation with the Stockholm Intergovernmental Forum (comprising representatives from Australian Government and State and Territory government agencies) and the Stockholm Reference Group (comprising representatives from industry, environment, primary producers and health sectors);
- National Action Plan for Dioxins – the National Action Plan for Dioxins outlines actions that Australian governments will undertake that are broader than reducing and eliminating releases of dioxins as required under Article 5 of the Stockholm Convention on Persistent Organic Pollutants;
- Scheduled Waste Management Plans – waste management plans have been developed for polychlorinated biphenyls (PCBs – 1993), hexachlorobenzene (HCB – 1996) and organochlorine pesticides (OCPs – 1999). These plans specify threshold concentrations, threshold quantities and notifiable quantities for each of these three chemicals;
- Chemicals Action Plan for the Environment – the Chemicals Action Plan (CAP) was endorsed by the Environment Protection and Heritage Council in June 2007; the CAP outlines agreed steps to be taken by Commonwealth, State and Territory environment agencies to implement the National Framework for Chemicals Environmental Management (NChEM).

iii. Coordination of projects with shared benefits

The Department also has taken a lead coordination role on initiatives which have had shared benefits with a range of stakeholders:

- ChemCollect – ChemCollect was a nationally coordinated scheme for the collection and safe disposal of unwanted and deregistered agricultural and veterinary chemicals, particularly OCPs, from farms during the period 1999 to December 2002. By the completion of the program, approximately 1670 tonnes of unwanted chemicals were recovered from rural areas and market gardens. While most of the collected stocks have now been destroyed using appropriate environmentally sound destruction technologies, some intractable chemicals remain in storage because it is uncertain whether Australia has a suitable facility for their destruction;
- National Chemical Information Gateway and National Chemical Reference Guide – the Department's website hosts two significant on-line portals containing chemicals information. The first is the National Chemical Information Gateway, which provides a wide range of links to information for stakeholders and the general community in a range of categories. The second is the National Chemical Reference Guide, which provides Australian and international guidelines and standards information on 645 chemicals. Together, these resources provide enhanced public access to chemicals information;
- Brominated Flame Retardants – in 2006 the Department released the results of three studies into the levels of a class of brominated flame retardants (polybrominated diphenyl ethers or PBDEs) in aquatic sediments, indoor environments and human blood. The aim of these studies was to improve our knowledge about PBDEs so that governments were in a better position to consider appropriate management actions. The outcomes of those studies, which include the finding that levels are highest in indoor air, and in young children in particular, have since assisted the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to conduct an interim public health risk assessment on PBDEs;
- Evaluation of the effectiveness of the Stockholm Convention on Persistent Organic Pollutants – Australia and New Zealand are jointly responsible for coordinating Pacific sub-regional input into the evaluation of the effectiveness of the Stockholm Convention, which is due to be considered by the Convention's fourth Conference of the Parties in 2009. The Department will be the lead Australian contact in undertaking this evaluation and Australia's national evaluation.
- OECD Control of Chemicals Programme - As noted previously, the Department represents Australia at the Joint Meeting, which operates under the OECD's environment portfolio. The Joint Meeting is focused on work sharing and harmonisation, and delivers substantial benefits in facilitating international trade and promoting world's best practice for chemicals management. It is recognised as the international standard-setting body for guidelines, techniques and data requirements for assessing industrial and agricultural chemicals. In particular, the OECD Test Guidelines provide internationally accepted standards and templates for testing. These guidelines form the basis of Mutual Acceptance of Data (MAD) among all OECD countries, which means that any test adequately performed in any country according to an OECD guideline will be acceptable to all OECD countries as well as to additional adherents such as India and South Africa. This greatly reduces the burden on industry as well as animal testing. Other Commonwealth agencies take the lead on subsidiary groups under the Joint Meeting that relate to issues relevant to

them. Further details on use of international data and risk assessment in the international regulatory context are included in Appendix 2.

iv. Environmental assessments for APVMA and NICNAS

The Department conducts assessments of the environmental impacts of new and existing chemicals and products for the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). These assessments are conducted under contract to APVMA and NICNAS. The Department and the Minister for the Environment and Water Resources currently have no statutory role in providing advice on the safety of chemicals in the Australian environment.

v. Legacy chemicals and contaminated sites

There is currently no comprehensive national approach to dealing with dangerous legacy chemicals or contaminated sites associated with past use or production, other than some general guidelines set out in the National Environment Protection (Assessment of Site Contamination) Measure 1999. Similarly, there is no national agreement on the disposal of hazardous chemicals per se, or within articles, to landfill.

Management of these issues is largely the responsibility of State and Territory governments. However, they can become a concern for the Australian Government, such as the current example of the 22,000 tonnes of hexachlorobenzene (HCB) waste in Sydney, for which Orica applied for an export permit to send as waste to Germany for final disposal. The refusal of the provincial German governments to accept the waste has brought a renewed focus on Australia's capacity to safely dispose of hazardous chemicals within its borders and the ability of State and Territory governments to deal with such waste in areas under their jurisdiction.

vi. Environmental protection and land management

The Department has to deal with chemical contamination issues arising through its own management responsibilities. The most striking example is that of the Great Barrier Reef World Heritage Area. There are demonstrated impacts of pesticide and fertiliser runoff on the Reef. The monitoring programme for pesticides and fertilisers being conducted by the Great Barrier Reef Marine Park Authority is perhaps the largest single example of such monitoring for chemicals in the environment in Australia.

Comparison with other OECD countries

The principal reason for the regulation of chemicals is to protect human health and the health of the environment. Human health may be affected by the direct application of chemicals or through exposure to chemicals which have entered the environment. For this reason, understanding the behaviour of chemicals once they enter the environment is vital to securing both human and environmental health.

In the USA, the Environmental Protection Authority (EPA) performs the regulatory function of protecting both human and environmental health and deals with industrial and agricultural chemicals. The EPA's broad remit includes management of contaminated sites, hazardous

waste disposal, air quality, water quality, and significant research in the field of chemicals management including the development of new scientific methods.

> *"The mission of the Environmental Protection Agency is to protect human health and the environment. Since 1970, EPA has been working for a cleaner, healthier environment for the American people."*

In Canada, two agencies, Environment Canada and Health Canada share implementation of the *Canadian Environmental Protection Act, 1999* the primary legislation for managing chemicals in the environment. Decisions on chemical regulation are taken jointly by the Environment and Health Ministers. Pesticides are regulated by the Pest Management Regulatory Agency within Health Canada.

In both the USA and Canada, the regulatory agencies are large departments with a broad policy perspective and with access to a wide range of resources. Chemicals regulation is seen as an important element within the broader remit of ensuring protection for human health and the environment. From a practical point of view, the areas responsible for chemicals regulation can draw readily upon the infrastructure, databases, modelling resources, awareness of larger policy issues, the human resources, and the economies of scale of a large department. This is particularly important in conducting environmental assessments, as the same chemical can behave differently in different receiving environments, so it is vital to understand the nature of each receiving environment. Often, this can most efficiently be done by drawing upon information that has been gathered for other purposes, such as climate and water catchment modelling.

In Australia, the health and environment assessments for agricultural and veterinary chemicals (via APVMA) and industrial chemicals (via NICNAS) are currently conducted by the Office of Chemical Safety (OCS) in the Department of Health and Ageing and the Department of the Environment and Water Resources (DEW) respectively. This arrangement provides an opportunity for APVMA and NICNAS to gain some of the advantages of the US and Canadian systems through drawing upon the broader resources and policy perspectives of the health and environment departments. This input, however, depends entirely on the annual renewal of service level agreements with the respective regulators. There is no statutory requirement for the regulators to call upon the Environment Minister and the Environment Department to provide advice on chemical assessments, even where it is known that the environment may be affected.

This contrasts with the *Gene Technology Act 2000*, which requires that the Gene Technology Regulator must seek the advice of the Minister for the Environment and Water Resources, in recognition of the potential environmental impact of the release of genetically modified products.

A potential weakness in the current Australian system outside the mandate of the current Productivity Commission study is that, in Australia, environmental risk assessment is not required for therapeutic or medical goods or chemicals such as pharmaceuticals, even though these chemicals can be biologically active at very low concentrations and can readily enter the Australian environment.

Under current arrangements, the health and environmental assessments for agricultural, veterinary and industrial chemicals demonstrate international best practice as defined by OECD procedures. Australia participates with other OECD countries in mutually agreed assessments whereby other countries rely upon the quality of the assessment conducted by Australian agencies such as the OCS and DEW.

Nonetheless, there are several areas of contrast between Australia and major OECD economies that highlight weaknesses in the Australian regulatory system. Some of these weaknesses stem from the fragmentation inherent in the Australian system, with controls set by different sectors such as transport, agriculture and health, various Commonwealth regulators, and each State and Territory. Areas for improvement include, *inter alia*, the following:

i. Lack of technical underpinning such as a single national database for chemical information (including commercial-in-confidence information) and state of the art modelling tools.

Several OECD economies such as Denmark, the USA, Canada, Japan, and others, have developed sophisticated tools to estimate characteristics of chemicals in the absence of direct data, for the purposes of regulation. This has several benefits: it reduces the requirement on industry to generate data; it reduces the need for testing on animals; and it reduces timeframes to undertake screening and broad categorisation work. Several of these tools involve estimating behaviour of a molecule based on its similarities to other molecules for which there are actual data. Well-populated chemical databases are critical and integral components underpinning such tools.

Although Australia has data spread amongst the separate regulatory agencies (including several databases maintained by the regulators as well as publicly available databases such as those run by this Department: the National Chemical Information Gateway and National Chemical Reference Guide), so far Australia does not have a consolidated, integrated and fully realised chemicals database. As currently structured, the Australian regulatory system also lacks the resources to develop validated, complex chemical modelling tools (although the Department does use non-proprietary components of tools developed overseas). Such sophisticated tools are becoming more relied upon as the norm amongst OECD countries, so Australia is at risk of slipping behind best practice. Although various agencies in Australia are pursuing arrangements with counterparts in other OECD countries to share expertise, this would be greatly enhanced if Australia had a more consolidated and committed base for maintaining technical excellence in the assessment of chemicals.

ii. The current chemicals regulatory system in Australia is "front end loaded".

The current regulatory system directs resources towards the assessment of risks arising from chemicals, but is unable to monitor the impacts on the environment of the use of the chemicals. Australia currently lacks a national monitoring programme to determine the fate of chemicals in the environment. Important assumptions made during the assessment process to estimate safety cannot be validated or revised through measurement data. Put simply, regulators make decisions based on the best available information at the time, but cannot be sure how accurately they assessed risks. They cannot determine the full risks to human health and the environment with certainty, as 'real world' feedback on the actual impacts arising from use is so limited. This situation is in direct contrast to the large long-running monitoring programmes underway in other OECD countries including Canada, Japan, USA, and South Korea. Such monitoring programmes also recognise that chemicals have the potential to become widely distributed in the environment, both nationally and internationally. Some persistent chemicals can travel long distances through the atmosphere and have been demonstrated to accumulate in areas and in species far from the original source, including the Arctic and Antarctica. Furthermore, in the absence of confidence about predictions, greater conservatism is necessarily applied in chemical assessments than might be required if better information were available. This brings obvious disadvantages for industry and users.

To be effective, regulation needs to be based on the best available science, which in turn requires good monitoring data:

- Recognition of this gap was made explicit as far back as 1990, with the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia recommending that the Commonwealth Government address this through regular monitoring. Several options to conduct such monitoring were explored and put forward in a report by Aquatech Pty Ltd in 1997;
- The *National Strategy for Agricultural and Veterinary Chemicals*, released by ARMCANZ in 1998, further reinforced the need for monitoring the fate of pesticides in the environment, in order to better evaluate risk, confirm the initial assessment and evaluate the effectiveness of controls. The situation was again reviewed by the Australian Academy of Technological Sciences and Engineering in 2002, in a report entitled *Pesticide Use in Australia*, which noted that the situation had not improved and made the explicit recommendation that a comprehensive integrated national environmental monitoring program should be implemented. However, this gap is yet to be addressed.

iii. Post-sale responsibility including compliance and enforcement

As identified in the Issues Paper, this area of Australia's regulatory system is weak and fragmented. Differing levels of and approaches to controls amongst the States and Territories have led to inconsistent implementation of recommendations and differences in how chemicals can be imported, supplied, used and disposed of. For example, for agricultural and veterinary chemicals, States and Territories retain legislative controls over storage and use of chemicals, licensing of spray operators in the case of pesticides and herbicides, as well as transport and disposal. The agency responsible for control of use varies between jurisdictions (eg health, environment, industry agencies). Also, jurisdictions use different regulatory approaches to the application of agricultural and veterinary chemicals (for example, chemical exclusions zones in Victoria, limitations on timing of spray operations in Tasmania, and mandatory buffer zones around sensitive crops for some chemicals in WA).

For industrial chemicals, each State and Territory has particular rules for their storage, sale, handling, use and disposal. There is no clear or consistent link between assessment recommendations made by NICNAS in relation to industrial chemicals and the implementation of these recommendations by the jurisdictions.

Although State and Territory environment agencies deal with the consequences of chemicals, they are not well resourced to do so and may have limited engagement with the direct regulatory agencies. From an environmental perspective there are still many communities who have outstanding concerns regarding chemicals in the environment, particularly pesticides such as atrazine and diuron. The focus on pesticides is not surprising since they are designed to be harmful to some life forms (that is, pests) and are actively used in the environment. The ongoing concern about chemicals in the environment is also a reflection of high profile chemical legacy issues in urban areas such as:

- high levels of dioxins in Sydney Harbour which has outraged the public and have precluded commercial and recreational fishing;
- brominated flame retardants detected in the sediments of Port Phillip Bay;

- serious groundwater contamination (by dioxins and other chemicals) in eastern Sydney (with an estimated clean up bill running to hundreds of millions of dollars); and
- the 22,000 tonnes of HCB stockpiled at Orica's Botany plant in Sydney.

These instances and past experiences in fish and bird kills, DDT, asbestos, lead paint and other situations highlight where the regulatory system has failed to meet the public expectation that the products available to them will not be harmful to them when properly used or when released to the Australian environment. What is not well known is the real extent of all our legacy issues and the extent to which such contamination is still occurring. For example, recent studies by the Department indicate high levels of brominated flame retardants in the blood of young children arising from furniture, furnishings and appliances which most Australian families still have within their homes. Without the capacity to confirm or deny the fate and persistence of chemicals in the external or indoor environment, these questions cannot be effectively addressed; nor is it possible to determine the level of compliance with directions for chemical use arising from risk assessment recommendations.

On a limited scale, the package of NChEM reforms agreed by Environment Ministers at the June 2007 meeting of the EPHC seeks to find ways, within the current regulatory system, to "close the loop" for chemical regulators so as to provide greater certainty on the implementation of control measures and some form of testing as to how effective those measures have been. The NChEM reforms, in conjunction with successful industry product stewardship schemes (such as drumMUSTER and ChemClear) and responsible care schemes (see PACIA submission), can make a valuable contribution to overall post-sale chemicals management.

iv. Access to information

As noted above, the Departmental website hosts the National Chemical Information Gateway and National Chemical Reference Guide, which provide a useful portal for information to the community. However, it is the Department's experience, through inquiries from the public, that the wider community is largely uncertain of how chemicals are managed in Australia.

In general, the public expects issues affecting the environment will be dealt with by the Environment Minister and issues dealing with public health will be dealt with by the Health Minister. The complexity of the current chemicals management system, and the absence of any statutory role for the environment portfolio, can be quite confusing for the general public.

Options for Improvement

In considering possible improvements to how chemicals are managed in Australia, the Commission could consider opportunities which could be realised through incremental change, and actions which would require major changes to the existing regulatory system.

Incremental Improvements

Incremental improvements which the Department believes are underway or could be implemented within the existing system if given appropriate support, include:

i. Improving access to better information for hazard and risk assessments so that the behaviour of chemicals in the receiving environment can be predicted more accurately. This would benefit environmental protection, industry and users by ensuring that the risk management measures are carefully targeted, being neither insufficiently protective nor unnecessarily restrictive. This also will reduce duplication of data requirements and accelerate assessment of new and existing chemicals;

   From an environmental perspective, this would be achieved by the development of a single national database for chemical information, better modelling tools, and improved access to existing environmental information such as catchment hydrology, soil types and wildlife information. It also would allow identification of regional differences in the behaviour of specific chemicals.

ii. Improving the monitoring of chemical behaviour in the environment. This would enable real world validation and revisions of assumptions made during the assessment process to estimate safety, and allow identification of potential future legacy issues thereby avoiding adverse health impacts and costly remediation. The benefits would include improved protection for human health and the environment and the ability to identify emerging problems at an early stage when they will be less expensive to fix. There would also be benefits to industry as it would enable more realistic scenarios to be assessed and appropriate refinements to safety margins, allowing assessments to be less conservative where appropriate. The data obtained through a monitoring programme would support better informed policy decisions, including responses to public concerns following actions taken in other countries on chemicals of concern. It would move Australia towards matching the long-running programmes established in other OECD economies for the benefit of public and environmental health. Public confidence in the safe management of chemicals would be enhanced.

iii. Implementing the Chemicals Action Plan for the Environment as endorsed by the EPHC.

iv. Confirming the role of this Department in the provision of advice on the assessment of the environmental impact of chemicals, for example, through an appropriate memorandum of understanding between relevant Ministers. This would not preclude scope for regulators outsourcing some components of assessment advice, but would provide a higher level of public reassurance that the environment is being protected through the involvement of the government's environmental agency. It would secure the benefits of access to wider Departmental resources and environmental policy perspectives for the statutory regulators.

Improvements which would require minor change to the existing system include:

i. Providing NICNAS with greater ability to ensure that its recommendations are ***implemented*** (comparable to the APVMA), as identified in the submission from the EPHC Standing Committee, to improve national consistency in controls on industrial chemicals. Minor changes would be needed to State and Territory legislation to adopt and implement NICNAS decisions. This would improve national consistency and predictability in managing industrial chemicals.

ii. Amending the legislation for NICNAS and APVMA to provide a requirement for the regulator to seek advice from the Environment Minister on the environmental impact of chemicals. This would ensure that the resources of the Environment Department

are brought to bear in the assessment of chemicals, and that legitimate community expectations of a role for the Environment Minister are met.

Major Improvements

The Productivity Commission Issues Paper asks:

Why has it been so difficult to achieve fundamental reform of chemicals and plastics regulation despite advice from numerous reviews and government efforts to address the concerns?

Several attempts have been made in the past to achieve significant change in Australia's system for managing chemicals. Some elements have been successfully introduced, particularly the agreement reached between the Commonwealth, State and Territory Government on managing pesticides that led to formation of the APVMA. Nonetheless, there remains a perception amongst many stakeholders that the chemicals regulatory system is overly fragmented, complex, confusing and inefficient. It is this perception that has led to the establishment of the COAG Task Force and the Productivity Commission Study.

The Department has not formed a view on whether the perceived failings require major reform of process and structure, but suggests that embarking on fundamental reform would require a willingness amongst all relevant stakeholders to work together on determining what a national policy for chemical management might comprise, and what the characteristics, principles and structure of an ideal regulatory system for managing Australia's chemicals might be within that overall national policy. In the Department's view, such a national policy should have clearly defined principles, functions and roles as well as quantification of costs and benefits. From an environmental perspective, a national policy would need to cover the full range of chemicals management activities from guiding involvement in international agreements on chemicals to the safe use and disposal of toxic chemicals within Australia, and an effective environmental monitoring programme. It would need to clarify public and private sector responsibilities and related financial and economic issues.

The establishment of clearly articulated principles and objectives for the regulatory system has been an important feature of several overseas systems, which has helped to provide benchmarks against which the system can be evaluated. Overseas examples such as REACH provide illustrations of the steps taken to develop national, and multinational, policies which in turn can lead to improved regulatory systems.

At present, most reviews in Australia appear to have been sectorally based (eg pesticides, industrial chemicals or therapeutics) and have been focused on addressing perceived problems within an existing regulatory regime. They have not looked, therefore, at possible changes at a broader level, encompassing other sectors and regimes.

Some have considered that fundamental change would be too difficult because of Australia's federal system, that is, only incremental change should be contemplated. While incremental change can deliver short-term improvements, it should not preclude consideration of more fundamental change.

Whether or not a national policy is developed, there is a need to consider whether the current regulatory system is producing unintended consequences. For example, one reason that the European Union spent several years developing REACH, their new regulatory system (Appendix 1), was the concern that requiring comprehensive safety assessments only for

new chemicals was entrenching the use of existing chemicals and discouraging the development of newer, inherently less hazardous chemicals.

In the context of the current study, the Department suggests that worthwhile incremental change within the current regulatory system (as outlined above) could be pursued in parallel with a structured national policy review process overseen by the COAG Taskforce. This process would bring together all relevant stakeholders, from at least the pesticides, veterinary medicines and industrial chemicals fields, to see whether there can be agreement on an improved national chemicals management model. If such a model can be agreed, the process by which it can be implemented, including any changes required to existing regulatory regimes, could then be addressed.

Areas where major change could be contemplated within the context of developing a national policy on chemicals management include:

i. Changes at the Commonwealth level

Examination of whether efficiencies in managing chemicals could be achieved by reducing the number of administrative regimes. One approach could include amalgamation of NICNAS and APVMA into a single regulator with access to advice from health, environment and other departments as appropriate. Potentially, this would bring economies of scale, pooling of skilled personnel, enhanced ability to resolve overlap and gaps in responsibilities for specific chemicals and the opportunity to critically compare the approaches taken in relation to industrial and agvet chemicals. In establishing a single body, this approach could benefit industry by providing a 'one-stop-shop' when importing, manufacturing, selling or using a chemical. On the other hand, there may be disadvantages to amalgamation, if industry or users perceive a single regulator to be less aware of or responsive to their particular needs and concerns.

The Department suspects, albeit in the absence of appropriate analyses of costs and benefits, that the greatest efficiencies and benefits from streamlining are more likely to be realised by both strengthening and reducing the complexity of regulatory arrangements at State and Territory level rather than changing existing Commonwealth structures.

Should changes at Commonwealth level be contemplated, however, the Department suggests that any new arrangement would need to take advantage of the full range of resources provided by the health and environment departments, and other agencies as appropriate. This could be achieved either by combining the regulators and having DEW and DoHA as statutory advisory agencies or by following elements of the Canadian model and investing the regulatory role jointly in the Environment and Health Ministers, supported by their respective departments. Both models would allow the regulator to draw upon the resources and broader policy context of the entire DEW and DoHA in provision of grounded, independent evidence-based advice. Variants of these models would allow additional Departments and Ministers to be involved in statutory or non-statutory roles.

ii. Rationalisation of Commonwealth, State and Territory roles and legislation

In addition to possible reforms to regulatory structures, the Issues Paper recognises inconsistency in how regulation is applied. Differing levels and approaches to controls amongst the States and Territories have led to inconsistent implementation of recommendations, and differences in how chemicals can be imported, supplied and used. Considerable time is spent on consultative mechanisms between the

Commonwealth and the jurisdictions, and with stakeholders. Such consultation would be significantly less burdensome in a structure that was less fragmented. Actions to achieve increased national consistency in whole of life of chemicals management (including health, environment and transport controls) could include:

- Improved exchange of information (eg through National Environmental Protection Measures), where national guidelines are set, but jurisdictions can take their own approaches to implementation (this is least uniform because it would not solve issues associated with inconsistency in implementation);
- A scheme whereby a national decision triggers State or Territory legislation, as outlined in NChEM (this would increase prospects for consistency, but actual implementation may still vary between jurisdictions);
- Model or template legislation that is incorporated by reference or "mirrored" in the Commonwealth, States and Territories – a submission by PACIA to this study noted that an existing successful model that would bear examination was that developed for the transport of Dangerous Goods for ADG6, which involved template legislation in the jurisdictions (this would increase consistency but there may still be differences in interpretation of the legislation); and
- Vertical integration of implementation powers – further referral of powers by the States and Territories to the Commonwealth for whole of life control of chemicals (this would further increase consistency, allow a clear and predictable progression from the assessment of chemicals to the implementation of any conditions on those chemicals, and lead to strengthened ability to enforce regulatory controls on use of chemicals). There may be significant benefits for the Australian community through assured implementation of recommendations aimed at reducing risks to human health and the environment. Having a single clear reference point on the requirements to safely store, manage, use and dispose of chemicals might result in greater compliance and improved chemical safety for the entire community. However, there would still be a need to deal with region-specific issues, so jurisdictions would need to continue to play a formal advisory and compliance role to ensure that the specific environmental and health concerns of each jurisdiction are taken into account.

Undertaking such reforms to structures and processes in the regulatory system may help reallocate existing resources to higher value functions, resulting in better protection for human health and the environment. However, the Department cautions against assuming that adequate resources exist in the current system to provide effective whole of life chemicals management. Merely rearranging the components may not be sufficient to produce a safe, effective system.

In summary, some of the opportunities for improving chemicals management in Australia could be realised through incremental change, as outlined in this submission. Whether incremental improvements will bring about sufficient gains in efficiency and effectiveness, such that major reform is not required, remains to be demonstrated. Other options for consideration include significant changes to the existing regulatory system, towards an integrated national policy for chemicals management. A process centred on development of national policy has the potential to address many of the issues identified by the Commission.

Appendix 1 - Overseas regulatory systems

It is clear that a number of the overseas regulators have invested a significant amount of effort and resources in developing a coherent overarching policy context and designing a cohesive and comprehensive system for managing chemicals. For example, both Canada and the EU have decided to take action on existing 'grandfathered' chemicals (chemicals already in use) now, in order to significantly reduce future costs associated with water treatment, clean-up of contaminated areas, and treating illnesses related to chemical exposure. This has led to significant restructuring of their chemicals management systems, as outlined below.

Regulation in Canada

Recognition of the potential threat posed by existing chemicals led the Canadian government to legislate to address the issue, and fund the health and environment departments to complete the technical categorisation process accordingly. A few hundred substances identified as being of particular concern will be going through a full assessment process and/or subjected to action. Other proactive measures are being undertaken, including assessment of the environmental risks posed by pharmaceuticals and personal care products. Greater detail is included in the following text, which is taken from the Environment Canada web site at:

http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html

> **Canada's New Government's Chemicals Management Plan** aims to improve the degree of protection against hazardous chemicals. It includes a number of new, proactive measures to make sure that chemical substances are managed properly.
>
> The plan aims to improve Canadians' quality of life, and better protect our environment. This plan will also improve the conditions for business in Canada by ensuring a level playing field and a predictable, science-based regulatory regime.
>
> Canada's Chemicals Management Plan includes:
>
> ***Regulations to address environmental risks posed by pharmaceuticals and personal care products***. The Government of Canada intends to work closely with stakeholders to complete the health and environmental assessments of more than 9,000 substances used in products regulated under the Food & Drugs Act. Food, drugs and cosmetics are currently regulated for their impact on human health. Improved regulations for these substances are necessary in order to identify and manage the risks these substances may pose when they are released in the environment (eg the release of large quantities of pharmaceuticals into water supplies). These new regulations will be implemented in 2010-11.
>
> ***Health monitoring, surveillance and research.*** Working with Statistics Canada, provinces and territories and other agencies, Canada's New Government will build a monitoring and surveillance regime that will track our exposure to toxic substances.

Sensitive species will be observed through an ecological monitoring program which will also serve as an "early warning" system for harmful substances in the ecosystem. In addition to identifying emerging substances that warrant attention, the program will ensure that we can measure progress on our actions.

Regulations and enforcement. The Government of Canada will be taking immediate action on five substance categories confirmed to be harmful to the environment and to human health in the long run, moving toward prohibiting most uses.

Challenge to industry. Categorization identified 200 chemical substances that are potentially harmful to human health or the environment that represent the highest priorities for risk assessment and appropriate controls. The Government of Canada will use existing tools and regulations to challenge industry to provide new information about how it is managing these 200 chemical substances.

Rapid screening of lower risk chemical substances. Categorization identified a number of lower risk substances that are unlikely, given current evidence, to pose a threat to the environment. These will be screened quickly using an accelerated screening approach that will apply a worst-case scenario to determine whether further assessment is necessary.

Accelerated re-evaluation of older pesticides. The Government of Canada will accelerate the re-evaluation of the remaining 200 older pesticides, targeted for completion by 2009. These re-evaluations are being conducted to determine if these pesticides meet today's health and environmental standards. Review and registration of new and reduced-risk pesticides, to potentially replace older pesticides removed from the market following a re-evaluation decision, will also be done more quickly.

Good stewardship of chemical substances. The Government of Canada is taking immediate and decisive action to address substances of high concern, and moving to reassure Canadians about substances that are of little concern. There are also more chemical substances that have been identified as requiring further assessment in future years. Canada's New Government is committed to assessing all of the substances that have been identified through categorization via successive rounds of assessment and, where necessary, regulatory action. Continuously improved information on the uses and effects of chemical substances will help establish these next rounds of priorities. This plan includes the investments needed to get this work started, and to keep Canada at the forefront of chemicals management globally.

The Government of Canada will improve product labelling programs as well as the way we deal with imported products which contain chemical substances prohibited in Canada. The Government of Canada will also look at ways to enhance its current monitoring of consumer products.

More information about the Chemicals Management Plan, including the list of substances to be addressed, can be found via the Chemical Substances Portal at http://www.chemicalsubstances.gc.ca.

Regulation in the European Union

The EU community has recently instigated REACH (Registration, Evaluation and Authorisation of Chemicals - the new law entered into force on 1 June 2007) which will encompass almost all industrial chemicals and provides a one stop focal point for chemicals in the entire EU. The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. It is also intended to stimulate and enhance the innovative capability and competitiveness of the EU chemicals industry by creating a level playing field for 'existing' and 'new' substances and encouraging substitution to less hazardous chemicals. REACH is based on the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health or the environment. The potential health benefits alone of REACH have been estimated in the order of €50 billion over a 30 year period.

In the 2001 white paper setting out the *Strategy for a Future Chemicals Policy*, the Commission outlined the result of a review of the current system and its new strategy for ensuring a high level of chemicals safety and a competitive chemicals industry.

The seven objectives that needed to be balanced within the overall framework of sustainable development were:

1) Protection of human health and the environment
2) Maintenance and enhancement of the competitiveness of the EU chemical industry
3) Prevention of fragmentation of the internal market
4) Increased transparency
5) Integration with international efforts
6) Promotion of non-animal testing
7) Conformity with EU international obligations under the WTO.

Reasons for REACH

The following text regarding the 2001 strategy is taken from the website at:

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

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> The present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date.
>
> There are some 3 000 new substances. Directive 67/548 requires new substances to be tested and assessed for possible risks to human health and the environment before they are marketed in volumes starting at 10 kg. For higher volumes more in-depth testing, focusing on long-term and chronic effects, has to be provided.
>
> While new chemicals have to be tested before they are placed on the market, there are no such requirements for "existing" chemicals which comprise more than 99% of the total volume of all substances on the market. This has been a barrier to

innovation within the EU chemicals industry by discouraging research and invention of new substances and favouring the development and use of existing substances over new ones. The number of existing substances reported in 1981 was 100 106, the current number of existing substances marketed in volumes starting at 1 tonne is estimated at 30 000. Some 140 of these substances have been identified as priority substances and are subject to comprehensive risk assessment carried out by Member State authorities under Regulation 793/93.

Thus, although some information exists on the properties and uses of existing substances, there is generally a lack of sufficient information publicly available in order to assess and control these substances effectively. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because the public authorities are responsible for the assessment instead of the enterprises that produce, import or use the substances. Furthermore, current legislation requires only the manufacturers and importers of substances to provide information, but does not impose similar obligations on downstream users (industrial users and formulators). Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce. Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Without test results, however, it is almost impossible to provide such proof. Final risk assessments have therefore only been completed for a small number of substances.

Under Directive 76/769/EEC, restricting the marketing and use of certain dangerous substances and preparations, the Commission has committed itself to carry out risk assessments and adequate analyses of the costs and the benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry. Indications of unacceptable risk (typically arising from notifications of restrictions at national level) are the subject of reports, which are peer-reviewed by the Scientific Committee on Toxicology, Ecotoxicology and Environment (CSTEE) of the Commission.

Current liability regimes are insufficient to remedy the problems identified in the Commission's review. Liability is usually based on the principle that those who cause damage should pay compensation for that damage. However, in order to be held liable, it is generally required that a causal connection be proven between the cause and the resulting damage. This is often virtually impossible for injured parties if cause and effect occur far apart in time and if adequate test data on the effects of substances are not available. Even if a causal connection can be established, compensation payments awarded by courts of EU Member States are generally not as high as, for example, in the US, and hence have a limited deterrent effect.

An authorisation system for uses of substances and the placing on the market of substances for such uses is established for the substances of very high concern. The substances selected for the authorisation system have hazardous properties of such high concern that it is essential to regulate them through a mechanism that ensures that the risks related to their use are assessed, weighed and then decided upon by the Community prior to actual use. This is justified because the effects of CMRs category 1 and 2 on humans are generally so serious and cannot normally be reversed so that such effects have to be prevented rather than remedied, and because PBTs/vPvBs accumulate in living organisms, so that accumulation would already

have taken place and could not be reversed if regulatory action were only taken *a posteriori*. The same applies to the other substances of equivalent concern that may be made subject to authorisation on a case-by-case basis.

In line with the general REACH approach, the requirements for the applicants under the authorisation approach are risk-based, as he has to demonstrate that the risks related to the use of the substance concerned are adequately controlled or that they are outweighed by socio-economic benefits.

Thus, the authorisation provisions ensure that risks from the use of substances with properties of very high concern are either adequately controlled or authorised on socio-economic grounds, taking account of available information on alternative substances or processes, in which case the authorisations will normally be time-limited. Substances of very high concern are defined as: substances that are category 1 and 2 carcinogens or mutagens; substances that are toxic to the reproductive system of category 1 and 2; substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and substances such as endocrine disrupters which are demonstrated to be of equivalent concern.

The authorisation provisions require those using or making available substances with properties of very high concern to apply for an authorisation of each use within deadlines set by the Commission. Deadlines shall be set for a number of substances at a time. These are normally those that are considered to pose the greatest current risk, in accordance with the criteria identified in the text. The intent is that those selected should be those with the 'Highest Expected Regulatory Outcome' (HEROs).

The burden of proof is placed on the applicant to demonstrate that the risk from the use is adequately controlled or that the socio-economic benefits outweigh the risks. Downstream users may use a substance for an authorised use provided they obtain the substance from a company for whom an authorisation has been granted and that they keep within the conditions of that authorisation. Such downstream users shall have to inform the Agency of this fact. This is so that the authorities are fully aware of how and where substances of very high concern are being used.

Appendix 2 – Risk based approaches and use of international data

Chemicals are regulated in OECD countries through a system of hazard identification and risk assessment in order to determine how individual chemicals might affect human health and the environment. The test results and expected exposure situations are then evaluated to determine how specific chemicals should be managed in order to control their risks. Use patterns and environmental conditions differ between countries and therefore so do risks. For example, soils in Australia generally have lower organic matter and lower cationic binding capacity than those in Europe and the US. Consequently, many chemicals may be less likely to bind to soils and more likely to migrate. In a number of cases, certain chemicals have been refused registration in overseas countries that are allowed here because the risk profiles differ. For example, differences in soil temperatures between Canada and Australia lead to significant changes to the expected persistence of fipronil (an insecticide) in the environment. Consequently, fipronil can be used in Australia but not in Canada.

The potential for large differences in risk according to uses and environmental conditions is well recognised internationally and for this reason one-size-fits-all risk assessments are not used internationally. It is therefore appropriate to avoid a generic approach to dealing with chemical risks. This is aptly illustrated in the recent industry reaction to the proposed classification of nickel compounds in Europe, leading to industry development of a targeted approach to risk assessment for metals (MERAG) which relies on a bioregional approach for assessment of the different risks posed by the same chemicals in environments with different water and soil characteristics.

Australia already makes extensive use of hazard data generated overseas, on overseas species through the OECD's Mutual Acceptance of Data. Although data on Australian species would be preferred in order to make a more accurate assessment of risks posed to Australian species, overseas data are accepted, which has greatly reduced the requirements on Australian industry for many years. Many countries, including Australia, are also involved in work sharing initiatives with the goal of utilising hazard assessments (but not risk assessments) conducted by other agencies that have been through an appropriate peer review process. It should also be noted that if Australia were to automatically adopt the decision of an overseas regulator to allow or refuse registration or notification of a chemical, then it could also lose the use of many chemicals such as atrazine, fipronil, fenthion, methyl bromide, 2,4-D esters, etc., as these are no longer registered in some other countries. In addition, the new authorisation and registration process of REACH is likely to remove a number of existing industrial chemicals from the European market.

Chemicals contained within articles and products: As a subset of the split of chemical regulation between four Commonwealth regulators, there are different approaches to regulation of chemicals when assessed as discrete substances, as opposed to when they are present in mixed products or within articles. Articles are considered to be items that are manufactured into a certain shape or design, and which do not change their chemical composition during use, and include such things as furniture and toys. Industrial chemicals are generally assessed as discrete chemicals, sometimes within a product, whilst agvet assessments consider the whole product that contains the chemical (because products can

contain numerous ingredients that may be toxic in addition to the active constituent). This approach is also largely also followed by international regulators.

Australia does not generally regulate the presence of particular chemicals in articles (eg the presence of brominated flame retardants in computers), predominantly due to the difficulties in identifying which substances may be present. For example, many articles or components are imported from overseas manufacturing facilities; in these cases the chemical composition of the article or component may be unknown or the component supplier may be unwilling to reveal the composition for commercial reasons.

Unlike the Australian system, the new EU REACH system will have the capacity to regulate substances in articles, including requirements to identify the presence of specific substances (although there will be some uncertainty as to what constitutes articles as opposed to containers with preparations). Under the EU REACH system, the article producers would have to list all the substances in the article – if they could not do so then they would either have to cease exports to the EU or change components to ones where all these details could be obtained and notified to the EU. The Productivity Commission could consider the advantages and disadvantages of adopting a similar approach for Australia.