



NCHEM DISCUSSION PAPER PUBLIC CONSULTATION SUMMARY OF DISCUSSION PAPER SUBMISSIONS



Environment Protection and Heritage Council EPHC Chemicals Working Group May 2007

Note

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SUMMARY OF DISCUSSION PAPER SUBMISSIONS

STAKEHOLDER COMMENT	RESPONSE		
Medicines Australia			
Applauds the move to a national framework for the management of environmental risks posed by industrial and agricultural chemicals in Australia and the proposed measures to ensure NICNAS has the legislative powers to improve environmental outcomes for such chemicals.	• Agree		
Concern that document flags future development of environmental risk management schemes for therapeutic goods - will need to be exhaustive consultation as well as a comprehensive risk-benefit analysis before the imposition of further regulation on the pharmaceuticals industry as this industry is most heavily regulated already.	NChEM focuses on industrial chemicals management. NChEM will provide for the future possibility of developing an environmental risk management approach for therapeutics. However, any future approach would only proceed through an open and transparent consultation process with all appropriate stakeholders; including detailed cost and benefit analysis.		
COAG principles of good regulatory practice should be considered before any further regulatory burdens on pharmaceutical industry that are not consistent with the objects of the Therapeutic Goods Act 1989: quality, safety, efficacy and timely availability of therapeutic goods.	The EPHC Working Group is committed to applying the COAG principles.		
Medicines Australia seeks an assurance that therapeutic chemicals will not be included in the environmental risk assessment manual and therefore subject to any new legislative burden without extensive stakeholder consultation and input.	The proposed environmental (ecological) risk assessment manuals give guidance only on how an assessment is undertaken for both industrial and agvet chemicals. The NChEM proposals do not place any new regulatory burdens on therapeutic chemicals.		
Dr Alison Bleaney			
Need consistent national standards and regulations across all States and territories.	The NChEM proposals aim to streamline environmental controls for industrial chemicals and to achieve nationally consistent actions relating to the implementation of NICNAS's recommended environmental controls by the States and Territories. The NChEM framework does not extend to other areas of chemicals management, such as health and OH&S.		
Environment and health bodies should share research and information	Agree. To some extent information is already shared across agencies. One of the objectives of NChEM is to improve and facilitate greater information exchange across agencies and jurisdictions.		

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Consistent risk assessment tools should be used across all jurisdictions	Environmental risk assessments of chemicals are conducted at the Commonwealth level and recommendations are implemented at Australian Government, State and Territory level.
	The Environmental Risk Assessment Manuals will inform jurisdictions, industry and public understanding of how environmental risk assessments are undertaken and how management recommendations are derived. The Manuals will provide a consistent assessment tool.
It is fundamental to constantly independently review all literature regarding areas that have been difficult to research e.g. immunotoxicity, endocrine disruption and epigenetic changes, and take action on new findings. Necessary regulatory changes should occur in a timely fashion.	Agree that science needs to be regularly reviewed and updated. This is primarily the role of the national regulators NICNAS and the APVMA, however NChEM may assist in this area through better identification and consideration of priority and emerging chemical environmental issues.
All chemicals that may impact on the environment need to be dealt with including cosmetic, therapeutics and food chemicals.	Agree. Where adverse environmental impacts may occur from a chemical, management controls may need to be assessed and considered. In the first instance NChEM is focussed on improvements to the industrial chemicals management system.
Priority should be given to chemicals that are persistent, bioaccumulative and toxic (including toxicity to the immune/endocrine/nervous systems and epigenetic mechanisms of toxicity).	Priority review criteria for individual chemicals are set by APVMA and NICNAS – NChEM proposes to establish a new process for identifying broad environmental chemical priorities and how they should be dealt with in a policy context.
Need a single national reporting system for all chemicals and an inclusive national data collecting system (for tracking environmental and human health effects including epidemiological studies).	Noted. NChEM, through its key area of information exchange, aims to ensure better collection and access to information about chemicals and the environment.
	The Australian Government Department of the Environment and Water Resources (DEW) is working to develop an environmental chemical monitoring database.
	The APVMA currently has an adverse effects reporting program (AERP) and NICNAS is considering the need for development of a post monitoring information capture system. NChEM proposes to integrate with these processes.
• Use of a toxic chemical should only be allowed if a cost benefit analysis deems its use necessary. Substitution should always be considered. The precautionary principle is fundamental.	NICNAS and APVMA consider use patterns for chemicals of concern under review and take these into account when making recommendations/decisions via the assessment process. NChEM may assist in this area through better

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			identification and consideration of priority and emerging chemical environmental issues.
		•	Working Group notes the Productivity Commission is currently undertaking a research project on the Precautionary Principle, which involves reviewing the concept and its policy implications. The expected release date of the project is August 2007.
V	eterinary Manufacturers and Distributors Association (VMDA)		
•	Supports NChEM principles and objectives and its focus on industrial chemicals.	•	Agree
•	Veterinary chemicals should not be grouped with agricultural and industrial chemicals as they are environmentally problem free.	•	Under the National Registration Scheme, all agricultural and veterinary chemicals must be assessed for the health, safety, environmental and trade risks, and registered before they can be sold, distributed or used in Australia. The areas within NChEM that look at the agvet system focus their attention on improving environmental input into the environmental risk assessment processes and improving communication and consultation among agencies across the Australian Government and states and territories.
•	VMDA requests that the term agvet used frequently in the Discussion Paper be eliminated entirely from all materials used by the Working Group.	•	Not agreed. The term "agvet chemical" is the accepted national terminology used by government, industry, chemical users and the public for those chemicals dealt with under the NRS established by Primary Industry Ministers across Australia in 1994.
•	VMDA asks that NChEM recognise the current registration and manufacturing (GMP) legislation for veterinary chemicals provides unique and adequate protection. This recognition has the foundation of manufacturers licensing and regular auditing which would intercept any emerging environmental problems in manufacture.	•	The Working Group recognises the Agvet Code and the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products. DEW's role in assessing the possible environmental effects of agricultural and veterinary chemicals for the APVMA is recognised. NChEM proposals aim to streamline state and territory environmental input into DEW assessment processes and to work with the APVMA on other possible refinements as set out in the NChEM Discussion paper.
•	VMDA expects NChEM to recognise the initiatives of Industry Self Regulation, AgSafe and particularly the industry funded ChemClear program which provides the facility for the collection of unwanted chemicals from farms.	•	Agree. NChEM recognises existing industry initiatives and provides scope for future initiatives.
•	Supports the risk based approach proposed under NChEM and objective that current assessment timeframes continue to be met.	•	Noted. NChEM aims to not impact on risk assessment timeframes for new or existing chemicals assessments.

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 National chemical assessment and registration processes should require that all new chemicals are tested for biodegradability within aerobic composting processes. 	The Working Group will refer the issue to the national regulators for consideration.
CropLife and Animal Health Alliance	
Commend a consistent national approach to the regulation of chemicals so that industry is provided with consistency, simplicity and certainty.	• Agree
 Concerned that could inadvertently create more burdensome regulatory system by: diminishing the role of science in risk assessment and priority identification; creating parallel identification and assessment systems to those that already exist effectively (e.g. APVMA system) tampering with already existing and effective system that operates for agricultural and veterinary chemicals. 	 The intention of NChEM is not to remove the role of science based risk assessments but to ensure that the environmental input into risk assessment is clear, comprehensive, transparent and robust. Individual chemicals of priority concern would still be subject to the rigorous science based review processes of national regulators. NChEM is not aiming to create a parallel identification program but rather identify environmental issues for national regulators to consider within their existing processes. Both national regulators, NICNAS and the APVMA, have indicated their support for seeking coordinated input on what the "environmental priorities" for future action are. The Working Group agrees that the NRS for agvets already provides most of the elements needed for best practice management of environmental impacts of agvet chemicals. NChEM proposals suggest minor refinements only and primarily related to improving environmental risk assessments by better coordination and consultation amongst different levels of government.
• Supports need to make assessments more transparent for the public (including industry). Such guidelines should clarify the linkages between international, national and state environmental standards. The Alliance and CropLife ask to be engaged in the development and upkeep of risk assessment manuals.	Agree. Environmental Risk Assessment Manuals will be made available for public comment. The Manuals will be living documents and can be updated at any time, following public, industry or government input.
DEW and states/territories should better coordinate themselves on environmental agvet issues and then feed into existing consultation mechanisms (RLC, PSIC) rather than attempt to change these working systems.	Agree that better coordination is necessary. The Working Group proposes to work with the APVMA, PSIC, and PIMC to consider and agree on the most effective coordination and consultation mechanism including better utilisation of existing systems.
Requiring registrant companies to supply use data is impractical and unworkable as registrants supply to wholesalers/marketers and have no link to users – and privacy requirements would hinder the transfer of data (cites).	The Final Report and Recommendations to the Director of NICNAS by the Existing Chemicals Program Review Steering Committee recommends that NICNAS examine the feasibility of a nationally co-ordinated system of

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Hormone Growth Promotant compliance program as e.g. of cumbersome, costly and ineffective program).	surveillance, monitoring and post market reporting. The EPHC Chemicals Working Group sees no value in pursuing any separate initiative, but sees major policy and resource benefits for all players in working together to further examine the issue.
Supports primary EPHC focus on establishing a credible and cohesive industrial chemical regulatory system. APVMA systems can provide a model.	• Noted
Will be active participants in roundtables.	• Noted
Western Australian Department of Health	
Department endorses the proposal to establish a more streamlined, transparent and nationally uniform approach to chemicals management to improve both environmental and human health outcomes. The procedures outlined in the paper provide a good basis for meeting these objectives.	• Agree
• Department strongly supports the inclusion of health risk assessment as part of the broader risk assessment process to address the human health impacts of chemical mismanagement and prevent this occurring in the future. However, there appears to be confusion in the document as to its scope. There is reference to the public health implications of chemical mismanagement; however, the action areas do not clearly identify strategies to address this. This may be resolved through the adoption of clearer definitions of the terms 'environment' and 'environmental risk' to specify whether these terms include humans and human activity. Greater clarity is also suggested for the terms 'environmental harm', 'precautionary regulation' and 'impacts'.	Public health and OH&S risk assessments of industrial and agvet chemicals are already undertaken by the Office of Chemical Safety. DEW undertakes environmental assessments on the environmental effects of chemicals on behalf of NICNAS and the APVMA. The national regulators consider all these assessments together. NChEM relates to environmental (ecological) risk assessments and will ensure that State and Territory environment agencies are able to have early input into assessments and that consistent and enforceable actions are taken at Australian Government and state/territory levels in response to federal regulatory agency recommendations. Terms requiring clarification are noted.
It is accepted that in some cases, environmental indicators of chemical burden are more sensitive than human health indicators. However, there is a need to protect public health where no environmental indicator exists. Consideration of the implications for public health as part of the risk assessment process would be an appropriate way of addressing this	Covered by the public health risk assessments currently undertaken by the Office of Chemical Safety.
• There are environmental health publications that could guide this process including the enHealth Council's 'Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Hazards' of 2002. This document establishes a rigorous approach to health risk assessment that has been adopted Australia wide. Environmental health representation	Noted. Existing risk assessment guidelines/models have been considered in drafting Ecological Risk Assessment Manuals.

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throughout the risk assessment process is imperative and would facilitate this process.	
• Incorporation of health risk assessment in the NChEM framework would provide for health risk assessment of a broader range of chemicals than is currently undertaken. Current systems are limited to addressing exposures to specific groups of chemicals, such as pharmaceuticals and food additives, while many other chemicals, which result in human exposure, are not regulated to the same degree. NChEM provides an opportunity to address this gap.	Health risk assessment is already incorporated into the national chemical assessment regimes of NICNAS and APVMA. NChEM aims to supplement this by improving the environmental (ecological) side of the risk assessment process. There is significant stakeholder interest in improving the links between environmental exposure and health, and the Working Group will be seeking further advice on how this could be done.
• The paper identifies improvements to policy and legislative frameworks as central to developing a more streamlined, transparent national approach. Clarification on how this objective is to be achieved is required including proposals for legislative amendments. There is also a need to clarify whether chemical assessments in Australia will duplicate the assessment outcomes achieved in other jurisdictions or contribute to the global knowledge base.	Further detail concerning possible legislative amendments will be considered and discussed with input from stakeholders. Links between chemical assessments undertaken in Australia and in overseas countries are explained by APVMA and NICNAS in individual assessment reports and in their organisational policy documents.
Australian Chemical Trauma Alliance	
Individuals with MCS and children are not protected from toxic chemicals by current regulatory authorities.	NChEM relates to impacts on the environment but recognises the close relationship to human health, particularly impacts on more vulnerable groups.
 Cites numerous books/studies about MCS and chemical impacts on children's health and lists policy suggestions from them including: pre-market screening of new chemicals for potential effects on the physical or brain development of children; thorough/mandatory testing of chemicals produced in high volumes to which children and childbearing adults are routinely exposed; labelling at point of exposure; better pollution reporting; exposure and disease monitoring; monitoring and reduced release of toxic chemicals to the environment; monitoring and reducing exposures (biomonitoring an invaluable tool); tracking childhood diseases that may be chemically related; improving scientific knowledge; increasing the awareness of the role of toxic chemicals in children's health. 	EPHC has already taken action to better inform the community on chemicals. Actions include: National Chemicals Information Gateway, National Chemical Reference Guide and an education campaign on chemicals in the household, currently under development. Many of the issues listed are broad policy issues which can be considered under the priority and emerging chemical issues approach that NChEM aims to establish. There is significant stakeholder interest in improving the links between environmental exposure and health, and the Working Group will be seeking further advice on how this could be done.

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DuPont Australia			
Agrees that reducing fragmentation amongst regulatory agencies will significantly reduce red tape	• Agree		
Need to fully detail and model all proposed changes so they can be fully costed	The Working Group is undertaking a cost benefit analysis for the NChEM proposals. Some individual companies have agreed to assist in providing information to inform the analysis, including DuPont, and the Working Group greatly appreciates their contribution.		
 Need clear statement on how NChEM changes will be funded. • 	The outcomes of the cost benefit analysis will inform this.		
Not clear how cooperation will be assured between Australian Government and S/Ts given history of disputes between levels of government	NChEM proposals have the cooperation and agreement of all levels of government		
 Suggests that the NICNAS-State MOU be improved to provide better communication between NICNAS, DEH and the State EPA's. 	Agree. This was an issue identified as requiring attention during NICNAS's recent review of its Existing Chemical Review program. Working Group and NICNAS are together exploring improvements to the MOU.		
Governments need to agree in writing at the start to eliminate redundant functions between them.	All jurisdictions are committed to streamlining processes and functions.		
A new organisation structure to rationalise environmental regulation needs to be designed and stakeholders should be asked to provide input. Additional consultation on these matters is requested.	Options for streamlining regulatory approaches under NChEM will be developed with stakeholders. COAG has established a Ministerial Taskforce to review chemicals and plastics regulation, to be informed by a Productivity Commission (PC) study. NChEM proposals will be provided by EPHC to the COAG/PC study and finalisation of regulatory proposals will be informed by COAG outcomes. The EPHC Chemicals working group will be closely linked to this work through the NSW representative, the Minister for the Environment.		
Industry questions who will pay for the high level of bureaucratic oversight and reporting implied by NChEM?	Cost benefit analysis will address this issue. It is not the intention of NChEM proposals to create a burdensomely high level of bureaucratic oversight or reporting.		
Need to leverage existing human management and information reporting and service delivery systems not create new ones.	Agree. NChEM will seek to better leverage existing systems where this provides for the most efficient and effective outcome.		

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•	 DuPont notes that the Discussion Paper creates an impression that Australian's are faced with a high level of chemical risk due to widespread chemical use. DuPont further notes chemicals are: a. mostly used and consumed in cities, which occupy <5% of the total land area. b. An estimated 90% plus of the industrial chemicals are of low concern as defined by the LRCC. c. Australia has a low rate of chemical synthesis by industry compared to other OECD countries. 	•	It is agreed that most chemicals are used and consumed in cities, where human populations are centred and where impacts on the environment are concentrated through releases via diverse media such as STP's and vehicles. The WG notes that many chemicals have dispersal mechanisms that allow them to move through the environment and have wide-ranging effects. It is noted that the criteria used for the LRCC proposal are strictly for identifying new chemicals that trigger lower notification and assessment requirements and do not relate to existing chemicals used in larger quantities. Health and environmental effects have never been assessed for the vast majority of existing chemicals, low regulatory concern or otherwise. While Australia's rate of chemical synthesis in comparison with other OECD countries is low, usage rates are significant.
•	NChEM must be an integrated element of the complete suite of chemical regulation leveraging existing data collection and service delivery systems with seamless state federal inter-relationships whenever possible to avoid costly duplication.	•	Agree
•	NChEM must integrate into the long run view of The Trans-Tasman arrangements for Health & Environment	•	APVMA has an exemption to the TTMRA for agvet chemicals. NICNAS is exploring opportunities for the harmonisation of the regulation of industrial chemicals.
•	NChEM must integrate with global trading partners and GHS to allow Australia to be economically competitive as a member of the OECD.	•	GHS is one of a number of chemical issues which require consideration within and across all jurisdictions. The Australian government has committed to implementing GHS by 2008 and leads the Australian input.
•	NChEM must not add to the regulatory cost or record keeping burden of industry without ascertaining clearly that demonstrable high risk exists.	•	Costs associated with NChEM will be ascertained through cost benefit analyses.
•	NChEM must demonstrate that functional duplication will not occur and that the intentions for new powers are not over reaching the federal system or creating a larger total bureaucracy.	•	This is not the intention of NChEM. NChEM is designed to increase transparency, consistency and accountability and avoid duplication.
•	NChEM fails to mention the power to suspend, prohibit, phase out and restrict the use of chemicals already exist in the various State and Federal jurisdictions and have been successfully used. Nor does NChEM justify why the current system cannot be modified to produce the required data output. NChEM should provide examples of where existing systems has been coordinated, tested for	•	The powers referred to are not available to environment agencies in each jurisdiction, although they may be available to OH&S agencies. The Working Group believes that powers proposed for NICNAS are standard for modern assessment and regulatory agencies world-wide and already exist in other Australian chemical management regimes (e.g. agvet). The Working Group is

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functionality and failed, rather than ad-hoc create new partially overlapping systems at the federal state interface.	seeking to create a simple and effective model for national consistency in environmental chemicals management. Options will be discussed with Stakeholders in 2007.
DuPont questions whether NChEM will replicate assessment work done in the USA or Europe? Is this duplication the best use of resources?	NChEM does not plan to replicate work already completed in other jurisdictions. Assessments will continue to be undertaken by APVMA and NICNAS with service arrangements to DEW, the Office of Chemical Safety and the ASCC. Hazard data from overseas OECD chemical assessments could be used in assessments here, as long as the appropriate arrangements have been made between regulatory agencies and applicants. NICNAS is exploring ways to increase harmonisation.
NChEM appears not to recognize the outputs of the NICNAS Existing Chemicals review.	NChEM does recognise the Existing Chemicals Review program. The Working Group was represented on the NICNAS reform team and is working closely with NICNAS to ensure reforms are linked.
NICNAS already has post assessment information powers through focused secondary notification and declaring a priority existing chemical.	Noted. NChEM proposes that consideration be given to improved utilisation of powers where a need for post assessment information has been identified. This will be further discussed with stakeholders through Working Group input to the proposed NICNAS scoping exercise (identified in NICNAS's report on the review of its Existing Chemicals Review Program), to be undertaken in full consultation with stakeholders.
All aspects of the Manual of methods and the criteria should be available to challenge under administrative appeals tribunal.	Environmental Risk Assessment Manuals provide guidance and will be made available for public comment. The Manuals can be updated at any time, following public, government or industry input.
Specific comments:	
Action area 1 - assessment	
 The method of creating and editing these manuals must be open to criticism and challenge and not the domain of an insulated and potentially non-representative advisory group. These manuals should reflect OECD practice and not global best practice as outcomes must not place the Australian economy at disadvantage with production trending to leave Australia. The criteria of the manuals must be written as far as is practical using the GHS system of classification as proposed by the OECD. 	The Environmental Risk Assessment Manuals incorporate OECD practices and give consideration to the available environmental components of GHS

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state involvement in environmental assessment an excellent concept	• Agree
strengthening interaction with national regulators should be the essential tool of NChEM to potentially save cost.	Agree with need for strengthened interactions
 Action area 2 – controls NChEM unclear on how fed/state processes will work together. Suggests NOHSC model regulations as a good example. 	Noted – much of the detail behind the regulatory link binding states and territories to industrial chemical regulator is still to be developed. This is occurring through discussions with stakeholders and will be considered by COAG.
Applauds the suggestion for transparency as set out in control manuals – but controls must be scientifically justified.	Noted. The Control Manuals will set out the tools available to manage environmental impacts of chemicals, from existing regulatory requirements through to voluntary codes of practice, industry programs and education.
Action area 3 – information • APVMA system a costly failure.	DuPont's opinion on this matter is noted. Any problems with the functioning of the adverse effects reporting system should be directed to the APVMA. The Working Group is keen to work with the APVMA and stakeholders to identify areas for improvement.
Mandating routine information monitoring / gathering by industry is poor economics.	NChEM does not propose to mandate routine information monitoring by industry. NChEM suggests there should be capacity in the system to require post assessment information (from industry or governments) if such a need is identified. This will be further discussed with stakeholders.
Action area 4 - emerging issues	
Good science must be the driving force	• Noted
Australian Pesticides and Veterinary Medicines Authority (APVMA)	
The Discussion Paper under represents the agvet National Registration Scheme (NRS). The APVMA notes a number of concerns with the discussion paper and its proposals. These include:	Working Group members are fully aware of the NRS. The Discussion Paper focuses on industrial chemical regulation in particular as the area of potential greatest environmental gain.
- Potential imposition of post registration reporting requirements which may not be compatible with current legislative obligations to be 'satisfied' of environmental risk prior to making a registration decision.	This policy area is still under development and will be further discussed with stakeholders. In the first instance, the Working Group intends to contribute to the proposed NICNAS scoping exercise (identified in NICNAS's report on the

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	review of its Existing Chemicals Review Program) for industrial chemicals post-surveillance and monitoring.
- Lack of clarity as to how each key action area supports the COAG agenda to reduce regulatory burdens.	NChEM aims to replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.
APVMA feels that these issues should be addressed in any future submissions EPHC may make to COAG or other Ministerial Councils.	• Noted
General comments: largely related to explaining the current NRS; and outlining current APVMA processes and obligations:	
Role of NRS state coordinators could be better recognised and utilised under NChEM	Agree. Working Group and APVMA have also agreed that State/Territory environment agency input into APVMA issues will also be streamlined by more effective use of DEW as a central coordinating point.
Importance of agvet labelling should be recognised.	Agreed and recognised.
Specific comments:	• Noted
 Assessment Manuals strongly supported. APVMA interested in linking its own manual with NChEM's 	
S/T assessment input – increased S/T involvement could add complexity to the assessment process, could increase timeframes and add to industry costs. Current APVMA system works well and reform not needed	NChEM aims to improve environmental input into the assessment process by coordinating state and territory environment agencies input at an early stage. NChEM aims to reduce complexity by resolving potential issues up-front. Statutory timeframes will be met.
Strengthening S/T interaction with national regulators - supports development of MOU but believes communication / input best achieved by better use by S/Ts of state coordinators and better consultation between DEW and S/Ts	Noted. Suggestions for improved interaction with APVMA have been discussed by the Working Group and APVMA, and will be trialled using DEW as the central coordinating point for environment agency input.
Improving agvet assessments – asks for further detail on suggestions noting some are directionally appropriate (full life-cycle assessment including disposal), others not necessary (non-active/volatility – already assessed, post-registration reporting – APVMA must be satisfied before it registers a product), others unclear (what is meant by use of non-regulatory tools?)	Noted. This will be further discussed with APVMA.

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Information feedback – supports need for improvements (but not necessarily increased reporting as this may be counter to COAG directions). Open to working in cooperation on ways to improve the AERP	Support noted. Better State and Territory agency input to AERP is a key action under NChEM.
Priority and emerging – strongly supports any efforts to streamline how environmental issues can be fed into the APVMA priority review program.	Noted. NChEM aims to provide strategic and coordinated input from environment agencies to national regulators.
Environmental Defender's Office NSW	
Supports NChEM and need for a national approach to more comprehensively address potential environmental risks associated with chemicals.	• Noted
A variety of instruments, including economic incentives, voluntary approaches, interim management measures and regulations should be utilised to encourage the development of a sustainable chemicals industry in Australia.	 Agree. Such approaches will be detailed in the proposed Manual of Environmental Controls.
Considers that comprehensive changes would be required to ensure that a sustainable chemicals industry, which is international best practice, is established in Australia.	Noted.
Happy to be involved in ongoing consultation	• Noted
Specific comments: Risk assessment Supports strengthened methodologies and best practice manuals, increased consultation between regulators and agencies and improvements to agvet assessments.	• Noted.
Recommends that all chemicals that have not been evaluated should be considered potentially hazardous, and steps should be taken to gather all available data and evaluate these chemicals as soon as possible. - is unclear on how NChEM assists this process.	Noted. There are moves by NICNAS to advance the review of the 38,000 existing industrial chemicals. NICNAS has undertaken a review of its existing chemical review program to assist in this approach. NChEM can assist in identification of priority chemicals issues which are of environmental concern and feed this into the national regulators' processes.
Supports measures to expand the role and responsibility of industry to generate data.	Noted.

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Chemical by chemical assessments could be replaced by assessment based on chemical structures or uses	This comment will be referred to NICNAS and the APVMA.
EU leading the way on chemical reform via REACH	• Noted
• Increased producer responsibility for the full life-cycle of chemicals and products containing them is needed. This will encourage the development of chemicals and products which are safer and easier to recover and recycle. The use of public information policies on the life-cycle management of chemicals will further ensure that chemicals and products are developed, used and disposed of safely.	• Agree
• Substitution – supports policies to encourage "sustainable chemistry" – e.g. encourage research investment, promote import and production of environmentally friendly substances and products. Suggests: technical criteria for products; labelling strategies; phased restriction of hazardous chemicals; tax deductions for green research; reduced import fees for green chemicals or disincentives for use of hazardous chemicals.	Noted. NChEM proposes to establish a process to identify broad policy issues of environmental concern. These suggestions will be considered in that context.
<u>Controls</u>	
• Supports nationally consistent regulatory requirements for chemicals of high environmental concern. However, the 'streamlining' process aimed at 'reducing red tape' must not result in a lowest common denominator approach to chemical control. Where chemicals with potentially significant environmental health impacts are involved, a certain level of 'regulatory burden' may be an appropriate and necessary safeguard. The nationally consistent standards and controls should be consistent with international best practice.	Agree. Improved environmental outcomes are the principle concern of NChEM.
Legislative details and timing unclear.	Further details of any legislative amendments will be developed in consultation with stakeholders and provided as input to COAG. Finalisation will be informed by COAG (and associated Productivity Commission review) outcomes.
Support expanded NICNAS powers. In particular, EDO supports NICNAS power to phase out, suspend, restrict or prohibit the use of high risk chemicals.	Noted. The question of expanded NICNAS powers has been referred to COAG for consideration.
EDO submits that comprehensive consultation and review be undertaken in each jurisdiction to ensure that adoption and enforcement of NICNAS controls by State and Territories does not undermine or weaken any effective controls	NChEM does not aim to undermine or weaken already effective chemical controls, rather to standardise their application across jurisdictions.

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already in place. As noted in the Discussion Paper, not all States have dedicated environmental chemicals legislation.		
<u>Informing decisions</u>		
• Supports S/Ts providing information to national regulators on the effectiveness of controls used to manage chemicals of high concern – this information should be made public.	• Noted.	
• Strongly support provision of post-assessment information for high risk chemicals. The Discussion Paper indicates that the information providers may be confident that the information will be provided as part of the chemicals management. It is unclear whether this is a policy position or whether there will be legislative amendments explicitly stating that such feedback must be taken into account. This should be clarified.	The Final Report and Recommendations to the Director of NICNAS by the Existing Chemicals Program Review Steering Committee recommends that NICNAS examine the feasibility of a nationally co-ordinated system of surveillance, monitoring and post market reporting. The EPHC Chemicals Working Group will work with NICNAS and stakeholders to further examine the issue.	
Priority and emerging	Agree. NICNAS has reviewed its Existing Chemical Review Program and a	
• EDO particularly concerned about PBT chemicals. EDO acknowledges that risk assessment is a time and resource intensive process, however, it is essential that resources are provided to assess existing chemicals (as envisioned under the EU REACH scheme), rather than focusing solely on new chemicals. It is essential that the backlog of unassessed chemicals is addressed.	report and recommendations are publicly available on the NICNAS website.	
Clarification needed on proposed stakeholder priority setting forum in terms of the composition.	The most useful means of gathering effective input from stakeholders will be further discussed with stakeholders	
Prioritising of chemicals must be based on science, and not industry preference.	Noted.	
Plastics and Chemicals Industries Association (PACIA)		
Supports concept of a national framework.	• Agree	
 PACIA seeks a meaningful reform of chemicals and plastics regulation to drastically simplify existing arrangements, reduce the overall burden of regulation and achieve regulatory efficiency through an evidence-based application of risk management. The continuation of piecemeal and unintegrated approaches to chemicals and plastics regulation can only result in a lack of uniformity, complexity and high costs of compliance. 	NChEM aims to reduce the overall burden of regulation and achieve regulatory efficiency by replacing 8 separate State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.	

STAKEHOLDER COMMENT	RESPONSE
PACIA argues that reform is essential for the global competitiveness of the Australian chemicals industry and will help to underpin its important role in supporting other key sectors of Australian manufacturing.	Agree. The global competitiveness of the Australian chemical industry is an important issue, as is public, occupational and environmental health and sustainability.
Argues has been insufficient industry consultation to date.	The EPHC Chemicals working group has been consulting on the concepts of NChEM for some time, and has presented to many industry consultative forums, conferences and public meetings as well as circulating progress reports to stakeholders. Many details associated with NChEM have been further developed in collaboration with stakeholders by way of roundtable meetings in which industry has participated.
NChEM must wait for the Productivity Commission to undertake its review of regulation of the chemicals and plastics industry, and the COAG Ministerial Taskforce's consideration of that review.	NChEM regulatory proposals will be further developed in consultation with stakeholders and provided as input to the COAG (and associated Productivity Commission) review. Finalisation of regulatory proposals will be informed by COAG outcomes. The EPHC Chemicals working group will be closely linked to this work through the NSW representative, the Minister for the Environment.
General comments • Lacks detail	Noted. Many of the details behind the proposals have since been developed in roundtable discussions with stakeholders.
No information provided on potential costs and benefits	The NChEM proposals are being subject to cost/benefit analysis
Is a potential expansion of the current regulatory burden and added complexity for industry operations.	The NChEM proposal on linking environmental requirements for industrial chemicals from the national regulator to states and territories is not aiming to increase regulatory burden, but rather create a nationally consistent approach to controlling the risks of these chemicals. NChEM proposes to replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach coordinated across the jurisdictions. This would reduce the regulatory burden on industry.
Particularly concerned about proposed expansion of NICNAS powers, which runs contrary to Government's commitment to reduce the regulatory burden on industry. The question of an increased role for NICNAS brings with it the issue of who would fund such an expansion. NICNAS operates under a full cost recovery model, funded by industry.	The Working Group believes that NICNAS should have available to it the full range of management tools (regulatory, economic, policy, education) to manage identified environmental risks. These are standard tools of modern regulators and are available in other systems (e.g. agvets). The Working Group notes that NICNAS has referred this issue to the COAG Ministerial Taskforce's consideration of regulation of the chemical and plastics industry.

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	NChEM will be informed by COAG outcomes.
In addition to duplication, inconsistencies btween environmental legislation are another major concern – does the framework propose to address the current inconsistencies between State environmental controls?	NChEM will replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions. NChEM will not "overhaul" all environmental legislation in all jurisdictions, as chemicals management is only one component of the legislated environmental responsibilities of State/Territory environment agencies.
Specific comments	Noted. It is intended that all regulatory controls are clearly specified. Any
• The introduction of environmental risk guidance documentation setting out the regulatory and management controls is supported by PACIA. This should be implemented with clear delineation between regulatory compliance and 'best practice' tools. Supporting seminars and education programmes on the use of this manual should be within the existing cost framework, resulting in no extra costs incurred to industry.	supporting seminars and/or educational materials would be funded consistent with current agency responsibilities and resources.
• The use of a Manual as a management tool should also be flexible enough to incorporate new information as it becomes available. Should an environment agency recommend modifications of any controls or the guidance materials, there must be assurance that consistent and harmonised position with the States and Territories is adopted.	• It is intended that the Manual of management tools be a living document that is revised regularly. It is intended that a consistent position be agreed upon by all environment agencies prior to the implementation of any control, in consultation with the relevant national regulator (APVMA or NICNAS).
Little thought has been given on the framework to underpin implementation of the environmental hazard criteria in the United Nations GHS – expects PC study to give policy guidance on future Australian regulatory arrangements for the GHS.	Noted. Comments have been forwarded to relevant Australian Government agencies.
Proposals raise potential for further over-regulation and would add complexity for industry – much more detail is needed.	The WG will further develop proposals for simplified and streamlined regulatory controls for the environmental management of industrial chemicals in consultation with stakeholders.
Proposed expanded NICNAS powers may duplicate existing S/T powers – this is contrary to Government's commitment to reduce the regulatory burden on industry.	The powers referred to are not available to environment agencies in each jurisdiction, although they may be available to OH&S agencies for OH&S controls. The Working Group believes that powers proposed for NICNAS are standard for modern assessment and regulatory agencies world-wide and already exist in other Australian chemical management regimes (e.g. agvet). NChEM aims to replace 8 individual State/Territory systems for

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	implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.
 Model for dealing with NICNAS environmental recommendations different to how OHS and public health recommendations are currently dealt with, and could necessitate an accompanying regulatory impact statement for these recommendations - this would exacerbate complexities and could not be supported. Proposed expansion of regulation for the industry under the NICNAS program are made in the absence of preliminary or detailed regulatory impact information, necessary to consider in developing a position on these recommendations. 	• Streamlining environmental controls for industrial chemicals will aim to achieve a nationally consistent approach to the implementation of NICNAS recommendations relating to environmental management. The NChEM framework does not extend to other areas of chemical management, such as health and OH&S, however the COAG Ministerial Taskforce may be able to address some issues in these areas. The Working Group welcomes any specific industry proposals on how national consistency can be best achieved.
Proposal to expand NICNAS powers must be referred to the PC and COAG Taskforce.	• NICNAS has referred proposals to expand its powers to the COAG Ministerial Taskforce for consideration.
An example of the use of non-regulatory, voluntary tools used by PACIA members is the Responsible Care program, a management system to improve health, safety and environmental performance. A series of industry Codes of Practice cover the life cycle management of the chemical, and include a specific Environmental Protection Code.	Working Group members are aware of these voluntary industry approaches and commend industry for them. NChEM will provide opportunity for future industry and industry/government partnership approaches to environmental chemical management.
Information proposals contain overlaps with issues identified in NICNAS Existing Chemicals Program Review	The Working Group has been working closely with NICNAS on possible reforms under both NICNAS and EPHC processes. The intention is not to duplicate but complement.
Proposal to access downstream sectors needs further analysis to demonstrate how this would be done feasibly and cost-effectively - need for information capture system not demonstrated and a model not defined. This proposal should be linked to the NICNAS review proposal carried forward as agreed in that context (i.e. should focus on identifying the circumstances in which downstream use information is deemed necessary) and a thorough feasibility and cost-benefit analysis undertaken.	The Final Report and Recommendations to the Director of NICNAS by the Existing Chemicals Program Review Steering Committee recommends that NICNAS examine the feasibility of a nationally co-ordinated system of surveillance, monitoring and post market reporting. The EPHC Chemicals Working Group sees no value in pursuing any separate initiative, but sees major policy and resource benefits for all players in working together to further examine the issue.
The proposal to use "information capture" systems is offered in the absence of any prior assessment of the effectiveness of existing surveillance schemes, and without cost-benefit information on developing a post-market surveillance, monitoring, and reporting system for industrial chemicals. The need for such a system is not well defined in the Discussion Paper; the assessment of other alternative mechanisms, using established reporting through, for example,	 The Working Group would be seeking to ensure a number of principles are reflected in any information capture system for industrial chemicals, these include: involvement of industry, community/environment and government players in both program design and the subsequent

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workplace chemicals legislation, or Poisons Information Centres, is similarly not available.	 contribution/collection of information system builds on existing chemical information holdings/reporting systems where possible system is simple and cost-effective for all to use potential uses for collected/collated information are clearly defined aside from those matters that are genuinely confidential, there is a mechanism for information to be publicly accessible that the system be comprehensive – i.e. single collection system and not multiple separate information holdings.
For identifying priority issues, supports application of sound science through transparent criteria developed with major stakeholders.	NChEM proposes to establish a process for identifying environmental chemical policy priorities in further consultation with stakeholders
Proposal to use the capacity of Environment Ministers to take direct action contradicts earlier proposals to provide NICNAS with powers to "control, suspend" etc	NChEM proposals to identify, prioritise and deal with environmental chemical priorities is being further explored with stakeholders. Actions to address chemical issues of concern could include the use of voluntary initiatives or product stewardship arrangements. Individual chemicals identified to be of high environmental concern would be referred to APVMA or NICNAS for consideration under their existing review processes, with advice sought on key milestones and timeframes.
Peter Thyer	
 Any chemical banned overseas should be automatically banned in Australia within one month Our isolation provides a good opportunity to avoid chemical contamination Organic produce should be an export growth area Sale of pesticides in cities and urban areas should be restricted as should sale of chemicals for DIY projects There needs to be a national programme of reducing chemical usage and the toxicity of chemicals used in turf management. Research into reduced/non chemical termite and locust control should be a priority New chemicals should only be allowed if they replace a higher toxicity chemical. 	NChEM proposes to establish a process to identify broad policy issues of environmental concern. These suggestions will be considered in that context.

STAKEHOLDER COMMENT	RESPONSE
The Shell Company of Australia	
Agrees with NChEM's aims. Shell also supports COAG principles of national consistency, prevention of duplication and reduction of complexity with regard to legislative review or development.	Noted. NChEM aims to replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.
More detail required about legislative changes and potential cost impacts.	EPHC Working Group is undertaking a cost benefit analysis for NChEM proposals. Proposed legislative changes will be further developed with stakeholders and informed by COAG and Productivity Commission review outcomes.
Assessment manuals must be flexible to accommodate new information as it becomes available	Agree. Manuals will be living documents and updated as necessary as new information becomes available.
Expanded NICNAS powers may duplicate existing S/T powers – contrary to COAG principles – needs more elaboration	• The powers referred to are not available to environment agencies in each jurisdiction, although they may be available to OH&S agencies. The Working Group believes that powers proposed for NICNAS are standard for modern assessment and regulatory agencies world-wide and already exist in other Australian chemical management regimes (e.g. agvet). The Working Group is seeking to create a simple and effective model for national consistency in environmental chemicals management. Options will be discussed with Stakeholders in 2007.
Manual of controls is welcome. This should be implemented with clear delineation between regulatory compliance and "best practice" tools.	• Agree
More detail needed about possible new information gathering requirements to be placed on industry	Noted. The detail behind the key area of information exchange is being further developed in consultation with stakeholders.
Should an environment agency recommend modifications of any NICNAS / APVMA controls, there must be a consistent and harmonised position across the S/T.	NChEM aims to replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.
Improved use of industry self-regulatory programs should be encouraged. Shell expects that any such self-regulatory programmes would be nationally consistent and that a definition would be supplied on what constitutes a membership body.	Noted and agreed. The proposed manual of environmental controls available will include voluntary and co-regulatory approaches.

STAKEHOLDER COMMENT	RESPONSE
Department of Human Services Victoria	
Supports the initiatives of the EPHC in reviewing current arrangements for the assessment of chemicals management which has in turn led to the development of the proposed framework outlined in the Discussion Paper.	• Noted
Also supports NChEM proposals because of the potential for improved protection of human health and the environment and for improved communication between government agencies and the community over chemical safety matters.	• Noted
ACCORD	
Finalisation of NChEM must wait for the Productivity Commission to undertake its review of regulation of the chemicals and plastics industry, and the COAG Ministerial Taskforces consideration of that review.	NChEM regulatory proposals will be further developed in consultation with stakeholders and provided as input to the COAG (and associated Productivity Commission) review. Finalisation of regulatory proposals will be informed by COAG outcomes. The Chemicals working group will be closely linked to the COAG/PC work through the NSW representative on the Taskforce, the Minister for the Environment.
EPHC efforts are to be commended but proposals are based on working within the status quo and this pre-empts PC and COAG work and perpetuates the ad hoc nature of all chemical reforms to date	The NChEM proposals are needed to fill significant environmental gaps. These gaps will exist in any management system, even if it is organised in a different way. While the NChEM proposals have been developed to complement existing systems and mechanisms, many of the proposals are sufficiently flexible to dovetail effectively with any modified regime.
ACCORD has consistently argued for real and meaningful reform of chemicals and plastics regulation to drastically simplify existing arrangements to reduce the overall burden of regulation and to achieve regulatory efficiency through an evidence-based application of risk management. Such measures are essential for the global competitiveness of the Australian chemicals industry and will help to underpin its important role in supporting other key sectors of Australian manufacturing.	NChEM aims to reduce the overall burden of regulation and achieve regulatory efficiency by replacing 8 separate State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions.
Need a comprehensive and expert national review (across all key policy areas, including public health, OH&S, transport & dangerous goods and the environment) that provides policymakers and stakeholders with a detailed, independent analysis of the impact on industry's competitiveness of the current	Being addressed by the COAG Ministerial Taskforce and associated Productivity Commission study.

STAKEHOLDER COMMENT	RESPONSE
system of regulation, along with recommendations for reform.	
ACCORD expects the COAG study to provide essential policy guidance, not for the development of the most appropriate model for an NChEM environm management framework, but also for future Australian regulatory arrangement in relation to other emerging areas of either new policy or potential policy change, including:	ent chemicals regardless of what broader policy changes may occur. This is the
 GHS; Poison scheduling arrangements for domestic and agvet chemicals; and Further clarification/reform for products at the interface between cosme and therapeutics. 	ics
Ongoing policy development for a national environmental chemicals management framework can continue parallel with the PC study but needs greater industry involvement.	Agreed. NChEM proposals can be further developed and provide important input to the COAG/PC study. The EPHC Chemicals working group will be closely linked to this work through the NSW representative, the Minister for the Environment.
Comments about the case study examples in the Discussion Paper (e.g. arguing that current regulatory system can adequately address these issues). Also comments that assessing the significance or otherwise of population biomonitoring data and acting on this assessment is primarily a public health agency responsibility and therefore any link to the NChEM proposal has to be considered tenuous.	proposals for consideration, comment and discussion.
 Argues that the Australian regulatory system already has the capacity to add potential public health concerns arising from chemicals through the priority review programs of both the APVMA and NICNAS. Also mentions that the National Drugs and Poisons Scheduling Committee process, conducted with the Dept of Health and Ageing portfolio, and involving the health department of all states and territories, also allows for ongoing reviews of domestic and agvet chemicals for both acute and chronic health impacts. 	and enhance these processes to ensure appropriate environmental outcomes are achieved.
 Also argues that formerly bad environmental management practices that characterised some members of the chemicals industry in the past are no long occurring, so there is no current justification for the imposition of the propose NChEM model, if corrective regulatory and self-regulatory actions addressin the actual origins of these problems have already been implemented. 	d regimes established by governments. NChEM is specifically designed to

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Argues that OH&S agencies do not support NChEM proposal for expanded NICNAS powers and thus a "holistic" approach to reform is needed (e.g. COAG review). Consistent whole-of-government positions both within individual jurisdictions and ultimately between Australia's governments are required.	Australian Government Department of Employment and Workplace Relations noted in its submission to the Review of NICNAS Existing Chemical Review Program that it did not support the expansion of NICNAS powers in relation to occupational health and safety issues. NChEM proposals focus on chemical effects on the environment and propose a need for expanded powers for the environmental management of chemicals. The Working Group has clarified issues with DEWR and notes that the question of expanding NICNAS powers has now been referred to COAG for consideration.	
 ACCORD questions why no mention of the existing Memorandum of Understanding between NICNAS and the States and Territories is made in the NChEM paper, particularly as it is an established principle of best practice for regulatory policy development that before suggesting any new proposal the proponent should assess options as to whether there is a possibility of making better use of existing arrangements. ACCORD wishes to know more about these arrangements, whether or not they are working, and if they are not, why? 	Agreed that improvements should be made to the existing links between NICNAS and environment agencies. Discussions are underway with NICNAS, including the potential role of the MOU.	
Instead of extending NICNAS powers, should make better use of NICNAS's existing MOU group – perceived failings are often the result of poor organisational use of communication and liaison processes. Better governance and accountability is required, not stronger regulatory powers.	See comments above.	
NChEM development can proceed in parallel to COAG but finalisation must be based on and consistent with COAG Ministerial Taskforce recommendations	Noted and agreed.	
Reiterated offer to work with EPHC Working Group to test NChEM concepts through a case-study approach. Wants increased industry involvement in NChEM policy development.	Appreciate assistance offered in relation to case studies and keen for industry involvement in the further development of NChEM.	
Environmental Health Committee (enHealth) of the Australian Health Protection Committee		
General support for NChEM proposals	• Agree	
• The use of the term "environmental risk assessment" to encompass effects on both biota and human health leads to an under-recognition in the document of the role of health agencies in such assessments.	Public health and OH&S risk assessments of industrial and agvet chemicals are already undertaken by the Office of Chemical Safety. DEW undertakes environmental (ecological) assessments on the environmental effects of chemicals on behalf of NICNAS and the APVMA. The national regulators consider all these assessments together. NChEM relates to environmental	

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	(ecological) risk assessments and will ensure that State and Territory environment agencies are able to have early input into assessments and that consistent and appropriate actions are taken at Australian Government and state/territory levels in response to NICNAS and APVMA recommendations.
Health agencies including enHealth, the National Health and Medical Research Council (NHMRC) and the Commonwealth Department of Health and Ageing should be specifically identified as partners in the NChEM process in relation to environmental health risk assessment.	The Department of Health and Ageing through the Office of Chemical Safety (OCS) already co-ordinates the health aspects of chemical assessments. NChEM proposals have been developed in close consultation and cooperation with OCS, in the Department of Health and Ageing. NChEM is designed to foster partnerships across jurisdictions and agencies. The Working Group is keen to enhance links with health agencies and welcomes suggestions for how this may best be achieved.
Where environmental risk assessment manuals cover health considerations, they need to be consistent with regulatory approaches and policies of the health agencies identified above. In particular, attention is drawn to the nationally agreed consensus document, "Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Chemicals" published by the Commonwealth on behalf of enHealth in 2002.	The Environmental Risk Assessment Manuals cover only ecological impacts.
Broader health input to NICNAS health risk assessments is needed to ensure a more consistent approach – suggests a possible NICNAS/State health liaison group	Noted. These comments will be referred to NICNAS.
 Health agencies such as the NHMRC should be tasked to establish nationally agreed approaches in areas of human health risk assessment, such as cancer risk assessment, where such approaches do not currently exist. 	These comments will be referred to the Australian Health Ministerial Council.
Suggest enHealth representative be invited as needed to national chemicals working group meetings, similar to NICNAS and APVMA.	A representative from the Health Ministerial Council was involved in the development of the National Chemicals Taskforce report. From time to time, representatives of other Ministerial Councils including Health, have been invited to Chemicals Working Group sessions, and this will continue in the further development of NChEM.
Are many un-assessed chemicals that health agencies have to deal with, such as trichloroethylene. Australia needs greater investment in chemical assessment. Current resourcing structures favour assessment of chemicals where there is a cost-recovery opportunity for quasi government bodies.	These comments will be referred to the national chemical regulators for consideration.

STAKEHOLDER COMMENT	RESPONSE
There is a shortage of skills in environmental health risk assessment and toxicology in Australia. Implementation of NChEM should include specific training positions to develop such skills.	The shortage of skilled and experienced risk assessors and toxicologists has been raised in a number of submissions. The comments will be referred to OCS and the national chemicals regulators. NChEM proposes to establish a process for identifying environmental chemical priorities and these comments could be considered in that context, given the need to better understand the links between environmental exposure and health.
NSW Minister for Health	
The protection of human health should be adequately considered before any changes to the existing chemical regulatory and assessment systems are proposed.	Environment Ministers have identified a need to improve the environmental aspects of chemicals management and will continue to pursue improvements to ensure best environmental outcomes via NChEM. The protection of human health is already integral to chemical management systems and will be augmented by NChEM improvements.
Public Health Directorate - Department of Health SA	
 The identification of issues and the need for greater rigour and transparency in environmental risk assessment of chemicals, and chemicals regulation is generally supported. 	• Agree
Seems to be confusion regarding interplay between environmental protection and environmental health. Need to refer to environmental assessments as ecological assessments.	Noted and agreed that better clarification of terms would be helpful.
• In terms of human health risk assessment, the need for a guidance document was recognised several years ago resulting in the publication of "Environmental Health Risk Assessment - Guidelines for Assessing Human Health Risks from Environmental Hazards" published by the Commonwealth on behalf of enHealth in 2002. This is a consensus document which followed extensive consultation with a wide range of national and international health and environmental scientists, risk assessors, epidemiologists, toxicologists and community representatives. It clearly describes how health risk assessments should be undertaken in Australia. EnHealth has produced a series of related publications dealing with environmental toxicology (i.e. The toxic impact of chemicals in the environment on human health - cf ecological toxicology, or ecotoxicology) and exposure.	Noted. Working Group is aware of health risk assessment work and has used it to inform NChEM proposals. The Working Group is keen to enhance links with health agencies and welcomes suggestions for how this may best be achieved.

STAKEHOLDER COMMENT	RESPONSE	
Draws attention to the problem of existing chemicals in the environment which have no sponsor to fund toxicological research on potential human health and ecological impacts. These so called 'orphan' chemicals present a real problem for State and Territory Health and Environment Departments in making risk management decisions for air, soil and water quality.	NChEM proposes to establish a process for identifying environmental chemical priorities and these comments will be considered in that context. Matters relating to health research may be better referred to health Ministers.	
NChEM needs to address the issue of the shortage of skilled and experienced environmental toxicologists in Health and Environment Departments nationally.	The shortage of skilled and experienced risk assessors and toxicologists has been raised in a number of submissions. The comments will be referred to OCS and the national chemicals regulators. NChEM proposes to establish a process for identifying environmental chemical priorities and these comments could be considered in that context, given the need to better understand the links between environmental exposure and health.	
• Important that NChEM is linked to environmental health – i.e. enHealth as this is the national health body that deals with environmental health management including the human health impacts of chemicals in air, soil and water	Agreed. The need for improved linkages between environment and health agencies has been raised by a number of stakeholders. NChEM proposals have been developed in close consultation with the Australian Government Department of Health and Ageing.	
Product Safety and Integrity Committee (PSIC)		
Supports the initiative to improve the environment risk management outcomes of Australia's national agvet chemicals management system.	Agree	
Potential for duplication if consultation coordination committee is established – more effective to use existing policy coordination committee and the involvement and cooperation is through PSIC and EPHC. Greater feedback and cooperation between environment and agricultural departments at the jurisdictional level is encouraged.	Noted. NChEM aims to reduce duplication. In relation to improved communication across governments. For agvet chemicals, it is proposed to better utilise existing structures, including PSIC.	
The performance management and reporting system currently being developed by PSIC will identify areas for improvement in the agvet chemicals management system and provide a transparent mechanism for reporting to stakeholders on performance. PSIC therefore strongly supports the development of the proposed chemical monitoring database, given that monitoring data on human health, occupational health and safety, environmental, chemical residue, food safety and trade impacts is needed to inform an effective performance management system. PSIC is represented on the steering committee oversighting the development of the database.	Noted. The Working Group will continue to work in partnership with PSIC, as appropriate.	

STAKEHOLDER COMMENT	RESPONSE
Supports moves to improve quality of the environmental risk assessments for agvet chemicals provided by the DEW, including improving the methodologies used. Supports State co-ordinators to provide input into the APVMA's decision making process, rather than individual environment protection agencies.	PSIC's position is noted. NChEM proposes that for agvet chemicals, environmental input into the APVMA's decision making process can best be achieved through state and territory environment agencies working more closely with DEW. Better liaison with state coordinators is also proposed.
PSIC is concerned that fragmentation of the National Registration Scheme could occur through the proposed splitting of responsibilities for risk assessment.	NChEM does not propose to split risk assessment responsibilities. Risk assessment will still be done by the OCS and DEW on behalf of the APVMA, as is the case now. State and territory environmental agencies will have an opportunity to feed any concerns about an individual chemical assessment (for those chemicals of high concern) through DEW to APVMA at an earlier stage in the process than currently occurs.
With respect to the proposal to expand the role of NICNAS to enable it to ban or severely restrict chemicals, a better alternative might be to develop nationally agreed environmental chemical standards for chemicals to be adopted across states/territories. This would provide a single list of banned or restricted chemicals, enforced by State/Territory EPA's or other agencies.	Proposals in relation to augmenting NICNAS powers have been referred by NICNAS to the COAG Ministerial Taskforce on chemicals and plastics for consideration. EPHC will work with COAG on this issue.
national training and accreditation scheme for higher risk chemicals is being developed and environmental considerations are being considered in that work.	Noted. The EPHC is represented on PSIC.
• The Agvet Code requires that the APVMA can only register a chemical product if it is satisfied that the use of the product in accordance with the approved label directions would not cause an undue environmental impact. Given this, and the fact that post registration monitoring requirements could affect the competitive nature of Australia's agriculture if the monitoring standards were more strict than those required by other major exporters of the same agricultural products, it may be more appropriate to use the PSIC performance standards that apply to environmental aspects to monitor the agvet chemicals management scheme's overall performance in this regard, rather than target specific chemicals.	Noted. NChEM proposes that the issue of post assessment/registration information be further discussed with stakeholders, including the national regulators.
The APVMA Labelling Code Working Group is currently working towards the development of revised codes of practice for the labelling of agvet chemical products based on agreed key labelling principles	Noted.
More consideration needs to be given to the costs associated with implementation of the NChEM framework, particularly in relation to monitoring which could be very expensive. Any requirement for post-registration	A cost-benefit analysis of the NChEM proposals is underway. Some individual chemical companies have agreed to assist in providing information to inform this analysis.

STAKEHOLDER COMMENT	RESPONSE	
monitoring should be subject to a cost/benefit analysis for each individual case and monitoring should only proceed where a clear need has been demonstrated.		
Arkema		
Supports basic objective to reduce fragmentation of regulatory agencies through an inter-governmental agreement on managing chemicals in the environment.	• Agree	
Pre-supposes all jurisdictions will agree on regulatory reform – history shows this unlikely	COAG is currently considering the regulation of chemicals and plastics. NChEM proposals will be linked to COAG considerations	
Needs more detail	Many of the reform concepts in the Discussion Paper have since been further developed with stakeholders in roundtable discussions.	
Proposal re NICNAS powers concerning – overlaps with other reforms – contrary to Government commitment to reduce regulatory burden on industry (Banks Report recommendations).	The Working Group believes that NICNAS should have available to it the full range of management tools (regulatory, economic, policy, education) to manage identified environmental risks. These are standard tools of modern regulators that are available to other management systems (e.g. agvets). The Working Group notes that NICNAS has referred this issue to the COAG Ministerial Taskforce's consideration of regulation of the chemical and plastics industry. NChEM will be informed by COAG outcomes.	
NICNAS is industry funded – but environmental outcomes benefit the whole community.	NICNAS needs to ensure that industrial chemicals available for use are not likely to harm the environment (or human health).	
Engineers Australia		
• In principle Engineers Australia supports any move to unify jurisdictional approaches to regulation. As such, Engineers Australia supports the establishment of NChEM, which will eliminate any variation in approach between the four existing agencies (NICNAS, APVMA, TGA & FSANZ).	NChEM aims to replace 8 individual State/Territory systems for implementing environmental management actions for industrial chemicals with a single approach co-ordinated across the jurisdictions. It will not eliminate any/all variations on any matters across the four national regulators (NICNAS, APVMA, TGA and FSANZ). Broader issues such as these could be addressed by COAG	
Engineers Australia believes that it is critical to the success of NChEM that close consultation between the various State bodies occurs to ensure nationally consistent implementation of environmental chemical management.	This is indeed critical and is one of the primary features of the NChEM proposals.	

STAKEHOLDER COMMENT	RESPONSE
It is important that the requirements established in the Environmental Risk Assessment Manual be consistent with, and include where necessary, the various Australian Standards relevant to the area of Risk Assessment (including but not limited to AS/NZS 4360, HB 436 etc).	Noted. Manuals will be public documents and stakeholder comments and suggestions will be welcome.
Engineers Australia would like to offer its assistance in the development of the Environmental Risk Assessment Manual.	Draft versions of the environmental risk assessment manual have been developed by DEW They will be open for public comment shortly. Engineers Australia's input would be welcomed.
With regard to the Manual of Environmental Controls, it will be critically important that this document be freely and publicly available to all users of chemicals, and other interested parties in Australia.	The Manual of Environmental Controls will be publicly available to anyone that is interested.
Engineers Australia would also like to offer representation in the development of the proposed Manual of Environmental Controls.	This Manual has not been developed yet. It is proposed to be a manual of tools (e.g. regulatory, economic, policy, education, voluntary and co-regulatory) utilised by jurisdictions to manage environmental chemical risks. The Manual is not proposed as a technical/engineering compendium.
• Engineers Australia gives some initial comments re the costs of implementing the scheme. It is proposed that simple risk assessments would take at least 30 man hours with more complex assessments likely to take up to 100 man hours per risk assessment.	Under NChEM, risk assessments would continue to be undertaken by the national chemical assessment agencies. Individual engineering companies would not have to undertake risk assessments.
It is not yet possible to speculate on the costs to chemical users until the Manual of Environmental Controls is released.	• Noted
• There is one area of NChEM that the Chemical College Board of Engineers Australia believes is lacking. It is noted that the documentation relating to NChEM focuses on the preventative areas of chemical assessment and regulation and does not extend to setting out a uniform national methodology for the response to chemical incidents with a view to limiting adverse impacts. Within the stated objective of improving environmental outcomes with respect to chemical incidents, this is a key area which should be included. Good risk management practice identifies hazards, determines the risk profile, implements controls and pre-empts emergency responses.	NChEM does not cover chemical incident response. Effective systems are already operating in all jurisdictions.
There will be cost savings to organisations which operate in different jurisdictions by unification of standards, but there will be no benefit in this regard to organisations which only operate in one jurisdiction. It is likely that	The Working Group is undertaking a cost benefit analysis for the NChEM proposals. Some individual companies have agreed to assist in providing information to inform the analysis. Any input provided by Engineers

STAKEHOLDER COMMENT	RESPONSE	
there will be costs of compliance for all organisations as the nationalisation of standards will likely impact all jurisdictions in some way. Preliminary consideration may be made by assigning a number of man hours per organisation, based on size and complexity of organisation, required to review and assess compliance with the changed standards.	Australia or member companies would be welcome.	
• Engineers Australia offers to contribute practical and informed experience to the implementation of NChEM. At this stage, the proposed process for setting risk management and regulatory controls for industrial chemicals (Appendix 3 of the Discussion Paper) involves determination and assessment by various Commonwealth, State and Territory agencies with community comment only being sought after NICNAS releases their draft assessments. The process should include input from industry and professional representation bodies (such as Engineers Australia) during the development of these assessments. We are therefore prepared to provide advice and/or support as may be considered appropriate.	Noted. NChEM aims to improve the links between environmental considerations and the operational practices of NICNAS. In this regard public consultation arrangements for assessment reports are the responsibility of NICNAS and processes are already in place.	
Department of Primary Industries and Fisheries Queensland		
The DPI&F supports the proposed NChEM initiative, specifically the four linked action areas of the key elements.	Agree.	
• It is understood that the proposals, once adopted, will ensure the Australian Government has the appropriate powers to restrict, review and remove undesirable industrial chemicals from the market. It is further understood that currently, the Australian Government does not hold such powers. This is an undesirable and untenable position.	The comments in the Discussion paper about regulatory powers at the national level relate to NICNAS, the national industrial chemicals regulator. The Working Group believes that NICNAS should have available to it the full range of regulatory tools that other national regulators currently have. Working Group notes that NICNAS has referred this issue to the COAG Ministerial Taskforce's consideration of regulation of the chemical and plastics industry.	
The DPI&F is very much aware of the need for the risks of agvet chemical use to be managed and supports initiatives to improve environmental outcomes in chemicals management. The Discussion Paper is not clear on how the proposed NChEM framework whilst focusing primarily on industrial chemicals, will extend to agvet chemicals. This is of concern given that a national scheme (the National Registration Scheme (NRS)) already exists for managing the risks (including environmental risks) of agvet chemical use.	Working Group members are fully aware of the NRS. NChEM does not intend to replace it. Risk assessment will still be done by the OCS and DEW on behalf of the APVMA. State and territory environmental agencies will have an opportunity to feed any relevant on-the-ground information and concerns through DEW to APVMA at an earlier stage in the process than currently occurs.	

STAKEHOLDER COMMENT	RESPONSE
• The Discussion Paper is targeted at environmental protection. However, on more than one occasion human health also appears to be the focus. Human health is dealt with by other government agencies separately to environmental assessments and considerations; therefore it is recommended that reference to health be removed from the document.	Noted. Human health assessments on agvet and industrial chemicals are done separately to environmental assessments. The areas are linked however, as a chemical may have effects on both health and the environment and effects on the environment can subsequently lead to human health effects.
• Throughout the paper there is mention of improved outcomes "for the community, the economy and the environment" (in this order). As the issue at hand is for better environmental outcomes from better chemical management, it would be more appropriate to list 'environment' first. It is the environment which provides for sustaining life from which communities and economies 'grow'.	Improved outcomes for all of these sectors are important. NChEM proposals focus particularly on improved environmental outcomes.
• It is noted that the proposed implementation of NChEM will be via existing Australian Government chemical assessment agencies, with State and Territory environment agencies carrying out the major effort of implementation. It is expected that State agencies will be sufficiently resourced to carry out what is understood to be the compliance based activities for industrial chemicals.	This is something which will be further clarified through the NChEM cost benefit analysis.
There is mention of the need for a national approach to the regulation of environmental impacts from 'high-risk chemicals'. A definition and/or the risk assessment process for the determination of high risk chemicals would be of benefit to the reader.	• Noted.
Current arrangements for managing chemicals by the APVMA, NICNAS, FSANZ and the TGA are mentioned in relation to the agreed frameworks for worker safety, human health, trade and dangerous goods. The APVMA also has environmental impacts of agvet chemicals assessed by the DEW.	Noted. The Working Group is aware of the APVMA's responsibilities in relation to the environment and is aware of DEW's role in environmental assessment of agvet chemicals. DEW is represented on the Working Group.
The need for updating the national assessment procedures and methodologies for environmental assessments of agvet chemicals is supported. This will ensure that national agvet chemical regulator environmental assessments are conducted using best practice international contemporary standards. However, this can occur within the existing system.	The Working Group agrees that the agvet system operates effectively and has proposed only minor refinements to improve environmental interactions within that system
DPI&F would like to receive a copy of the Environmental Risk Assessment Manuals, when they become available.	These will be public documents.