PUBLIC ROUNDTABLE DOCUMENTS

EPHC CHEMICALS WORKING GROUP
National framework for Chemicals Environmental Management
NChEM
ROUNDTABLE

PRIORITY AND EMERGING CHEMICAL ISSUES
THOUGHT STARTER PAPER
DECEMBER 2006

This thought starter paper focuses on the key area of priority and emerging environmental chemical issues. The EPHC Chemicals Working Group (the Working Group) is seeking input from roundtable participants to help identify a workable model for identifying, screening, prioritising and dealing with chemical issues of environmental concern. This proposal is not to replace, nor duplicate the existing chemical review programs that are in place by national regulators of NICNAS and APVMA. An outline of NChEM and key areas is at Attachment A.

Roundtable participants' input is sought to:

- develop the process(es), including criteria, necessary to identify and take action on priority and emerging chemical issues of environmental concern;
- identify how these should link into existing priority setting processes (e.g. for the APVMA and NICNAS); and
- identify which issues stakeholders are seeking to put on the table for initial consideration (eg to pilot some examples) against the agreed criteria/filtering process.

PART ONE: ELEMENTS FOR AN NChEM APPROACH ON PRIORITY AND EMERGING CHEMICAL ISSUES

Environment Ministers (EPHC) have agreed that a key component of NChEM should be a mechanism for dealing effectively and efficiently with priority and emerging chemical issues of environmental concern. A summary of stakeholder views on this component, obtained during the recent NChEM public consultation phase, is presented in Attachment B.

There are a number of key elements that need to be considered in developing a workable approach. These can be grouped into five areas:

1. What is the scope of the mechanism?
2. What sort of information should be considered?
3. Once chemical issues are identified, how should they be prioritised and selected for further consideration and possible action?
4. Who should lead the process and be involved in decision-making process (es), including expert/technical input. How should public input be built in to the process?
5. What are the appropriate outputs and actions for selected priority chemicals issues?

KEY ISSUES

In developing the most strategic and effective system for identifying and taking action on priority and emerging issues of environmental concern, a number of key questions need to be discussed. These include:

1. What is the scope/goal of the work?

The EPHC Chemicals Working Group aims to identify issues/chemicals, which are of environmental concern and an appropriate way forward to deal with the issues. This could include, for example, passing on its concerns to NICNAS or the APVMA (*the national regulators for industrial chemicals and agvet chemicals respectively*) or referring matters to EPHC for further consideration and possible action. Such actions could include voluntary and co-regulatory measures (*such as ChemCollect, DrumMuster, ChemClear or industry code of practice),* regulatory mechanisms, cross-portfolio liaison or requests for further information. The EPHC Chemicals working group is not aiming to duplicate the NICNAS or APVMA existing chemical review programs. For an outline of the existing chemical review programs of NICNAS and APVMA refer to Attachment C**.**

2. What are the inputs to determining priority or emerging chemical issues of environmental concern?

Input on issues could include information sourced from:

- Australian Government agencies
- State and Territory environment agencies
- Internationally recognised information[1]
- International regulatory action e.g. Stockholm (Persistent Organic Pollutants or POPS) and Rotterdam (Prior Informed Consent or PIC) Conventions
- Australian recognised research
- Input from community/industry/other stakeholders
- Media/Internet (e.g. alert to possible problem)
- Adverse experience or complaint data
- Monitoring/trend data

Recommendation

Information on priority and emerging chemical issues is likely to be provided from a wide variety of sources. *(See also discussion points regarding determining the credibility and robustness of information and obtaining stakeholder input)*

[1] Internationally recognized sources for example can include documents generated by the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the United Nations Environment Programme (UNEP).

Specific questions for response by Roundtable members:

1. What other information sources could be considered?
2. How would you screen/filter the information to ensure it is credible and robust?

3. <u>What criteria should be applied to determine if the issue is of a significant priority to warrant further consideration and action?</u>

There are many ways that chemical issues can be prioritised – as evidenced by the large variety of international systems. EPHC has developed 'filter criteria' for issues to be deemed suitable for the national agenda, and the Chemicals Working Group could adopt the concepts of these for application to chemicals management. The Working Group does not consider it appropriate to develop detailed technical criteria to evaluate environmental priorities. Such criteria are already established and reviewed from time to time by the national regulators (NICNAS and the APVMA), and the Working Group does not seek to duplicate this process or expertise. However, the Working Group (*and any appropriate technical advisory groups – refer to point 4*) may seek to have input to those criteria that relate to environment protection if it considers they need modification or strengthening.

The EPHC 'filter criteria' cover the following broad areas and these need to be refined to suit chemicals management. Preliminary input is sought in this paper, however it is expected that discussion of these would occur in a face-to face "workshop" in February 2007. Possible broad criteria include:

A. Defining the issue

- define and characterise
- factors to potentially consider – environmental, economic and social drivers
- actual and potential environmental/health impacts
- timeframe over which issue may extend
- geographical context – where is it a problem
- existing frameworks – can the issue be solved, what are the barriers, do current frameworks provide scope/mechanisms to address the issue
- what are the research needs
- who are the stakeholders that should be involved
- variations in factors across jurisdictions

B. Screening criteria

- What is the significance of the problem (eg severity of risks, any downstream consequences; short and long term implications; one-off or ongoing issue etc)
- What is the extent of the issue (eg geographic range, which jurisdictions affected, any trans-boundary issues, international impacts, priority in different jurisdictions, any local or regional factors such as land use, industry or environment)

- What is currently being done (e.g. reviews/actions by NICNAS or APVMA, international and other actions)? What are options for dealing with the issue
- Is there a role for government intervention (eg market failure, protection of the environment, protection of public health, public good, are existing legal and policy settings adequate, what are consequences of government inaction etc)
- Are there benefits from national action (if not already occurring)?
- Who has the powers, responsibilities and influence (eg Commonwealth, State and Territory roles and powers, international agreements, opportunities for working with national industry bodies)

C. Prioritisation

- significance of impact or harm
- opportunities for delivering environmental gains
- advantages and disadvantages of any action
- level of social and community concerns

D. Potential tools

When developing proposals for EPHC action on national chemicals management issues, consideration and evaluation of a range of different policy tools is needed so the tool most suited to addressing the issue can be identified and recommended. Options and approaches outside the EPHC/NEPC framework, including informal cooperation, should also be considered.

Recommendation
For the purposes of the NChEM proposal for determining priority and emerging chemical issues, the role of the EPHC Working Group should be to 'fine tune' and apply the broad EPHC criteria. (*Detailed chemical review and assessment criteria are already part of APVMA and NICNAS processes and would not be duplicated. The Working Group would like the opportunity to discuss and provide input to NICNAS and APVMA on those criteria from time to time, to ensure their adequacy from an environment protection perspective*)

Specific questions for response by Roundtable members:

1. Are the broad criteria reasonable and should any others be included?

2. What areas need to be modified to suit chemicals management?

4. Who should lead the process and be involved in decision-making process(es), including expert/technical input?

As noted in the discussion paper, NChEM, if agreed, would be the responsibility of EPHC (*i.e. implementing the NChEM agreement and reporting to COAG on progress*). It is expected that EPHC would establish a committee of officials (*replacing the current Chemicals Working Group*) to oversee the implementation process and monitor the effectiveness of NChEM as well as take over the work program of the current Chemicals Working Group. The proposal is that the committee would be made up of senior representatives from the Australian Government Department of the Environment and Heritage (DEH) and state and territory environment agencies.

The broad functions of the committee could include:

- developing an implementation plan with key milestones and performance measures, and reporting to EPHC on progress (including recommending any appropriate modifications)
- co-ordinating policy advice to EPHC on the environmental management of chemicals, and promoting whole-of-government approaches to managing chemicals and resolving issues
- actively working towards application of national environmental risk management controls for chemicals of concern, including assisting jurisdictions to make any necessary changes to their chemicals legislation or policies.

The committee could also be responsible for overseeing the priority setting mechanism, to identify and consider emerging and priority chemical issues of environmental concern, including facilitating stakeholder input into the priority issues process.

The committee could seek technical advice and other input from time to time and it is envisaged that it would set up advisory groups, as needed, to obtain this advice. This might include a technical/scientific group to review technical information on chemicals and update technical guidance materials, such as the planned Ecological Risk Assessment Manuals.

The committee could refer environmental chemical matters to other Ministerial councils and/or Australian Government assessment and regulatory agencies, where appropriate. The Committee would also be responsible for developing recommendations, policies, principles and guidelines on advice from EPHC to continually improve the ecologically sustainable management of chemicals.

Recommendation

The committee of officials charged with implementing NChEM and monitoring its effectiveness would be also responsible for overseeing the priority setting mechanism, with technical, public and other input provided as required.

Specific questions for response by Roundtable members:

1. Is this approach acceptable?

   Yes

   No – why not

5. How should public input be built in to the process?

The EPHC Chemicals Working Group has identified the need for facilitating greater community involvement in identifying and prioritising chemical issues.

Enhanced input from the chemicals industry, chemical users, academics and researchers, environment groups, all levels of government and the broader community would be facilitated through a possible stakeholder consultation forum held every one or two years. This would provide an opportunity for any interested groups or individuals to raise and discuss concerns about chemicals and could help generate ideas, innovations and co-operative strategies for more effectively dealing with chemical issues.

Recommendation

Provision for a public forum to be held every one or two years that aims to identify chemical issues. The forum would be inclusive with representation from a range of stakeholders, including: chemicals industry, chemical users, academics and researchers, environment groups, all levels of government and the broader community.

Specific questions for response by Roundtable members:

1. Is a public forum an appropriate and cost-effective means of gathering broad stakeholder input?

   Yes

   No – why not? What other options would be better?

2. Given there is likely to be a high volume of issues identified at the first call for input, what approaches could be implemented to successfully manage this initial workload peak? Are there successful processes/models to draw upon?

6. Once a chemical is identified as an environmental priority, what are the appropriate action paths for dealing with the issues?

Possible actions could be through

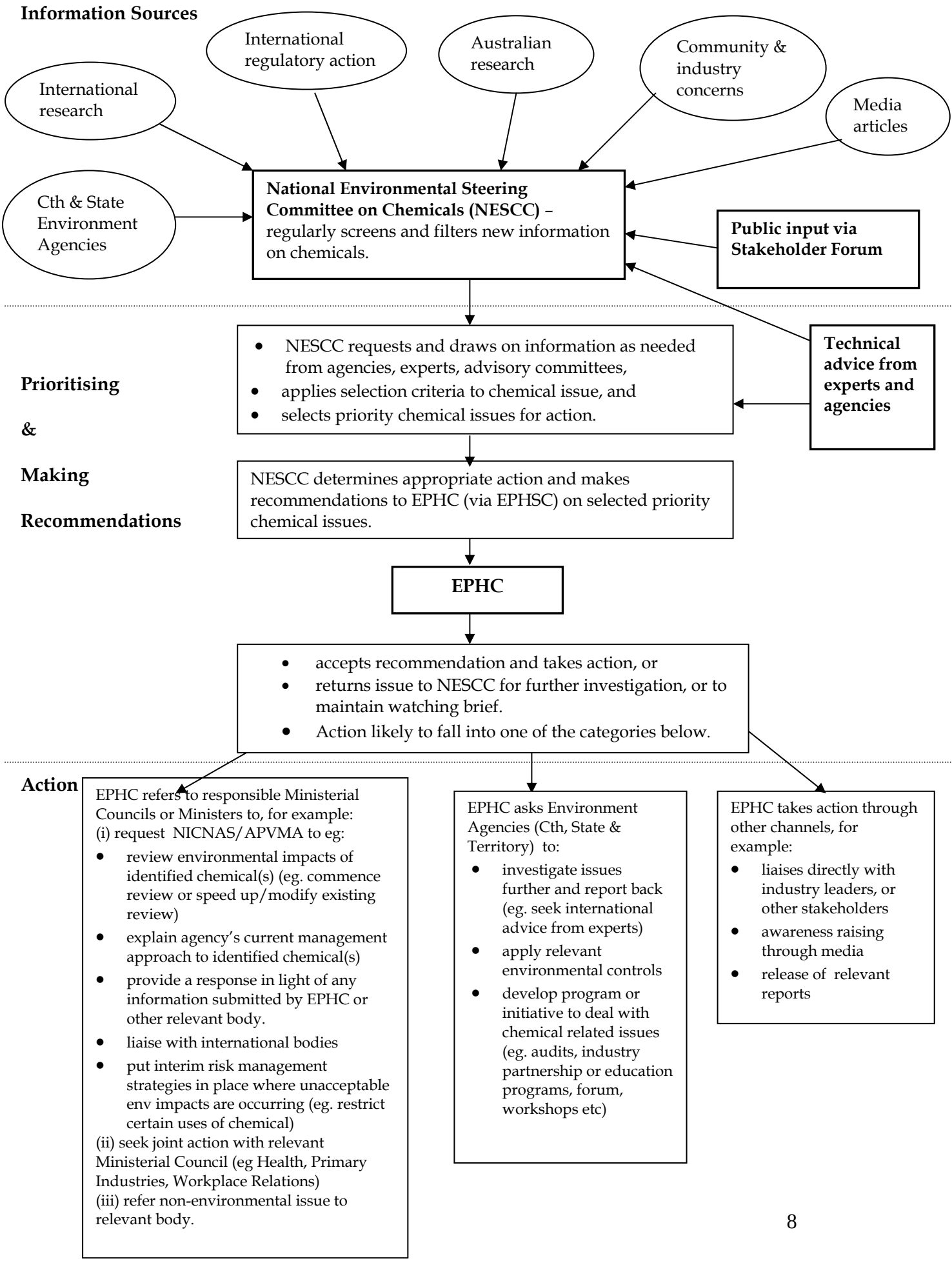
- EPHC and environment agencies
- other Ministerial Councils
- national regulators
- industry
- other stakeholder action.

The Working Group aims to utilise existing mechanisms and build on them (*as needed*) to develop an approach that is simple, transparent and delivers the strategic outcomes being sought. Figure 1 gives an outline of the broad approach for this key area, and actions that EPHC could take.

PART TWO: EMERGING CHEMICAL ISSUES FOR INITIAL CONSIDERATION

Some issues have already been identified by stakeholders as potential priorities and these are listed in the last dot point in Attachment B. These issues have been separated into "environment" issues versus broad chemical policy issues that require discussion amongst all relevant stakeholders. Roundtable members may like to raise additional issues as part of this thought starter or during the roundtable discussions. It may be useful to use some of these issues to pilot test the mechanism that may be established under NChEM.

Figure One: Broad approach to identifying priority and emerging chemical issues of environmental concern.



SUBMITTING COMMENTS ON THOUGHT STARTER

Please submit your comments via e-mail to:

Lisa Nardi at nchem.roundtables@environment.nsw.gov.au. Comments will be circulated to all roundtable members for their information so that informed discussion of all views can take place.

If you would like to discuss details of your comments with your EPHC Chemicals working group member in your State or Territory, contacts are provided below:

Contact	Telephone	Email
Australian Government		
Mr Lee Eeles	(02) 6274 1427	Lee.Eeles@deh.gov.au
New South Wales		
Ms Liz Moore/ Dr Jane Mallen-Cooper Lisa Nardi (NChEM project co-ordinator)	(02) 9995 5903	Liz.Moore@environment.nsw.gov.au Jane.MallenCooper@environment.nsw.gov.au Lisa.nardi@environment.nsw.gov.au
Victoria		
Dr. Barry Warwick	(03) 8458 2340	barry.warwick@epa.vic.gov.au
Queensland		
Dr Faiz Khan	(07) 3227 7349	faiz.khan@epa.qld.gov.au
South Australia		
Mr David Duncan	(08) 8204 2094	david.duncan@state.sa.gov.au
Western Australia		
Mr Doug Hide	(08) 6467 5378	doug.hide@environment.wa.gov.au
Tasmania		
Mr Mark Stanborough	(03) 6233 6290	Mark.Stanborough@dpiwe.tas.gov.au
Australian Capital Territory		
Mr David Power	(02) 6207 5311	david.power@act.gov.au
Northern Territory		
Mr Michael Lawton	(08) 8924 4031	Michael.Lawton@nt.gov.au

ATTACHMENT A

NCHEM GENERAL BACKGROUND

The EPHC Chemicals working group has been leading the work to develop a proposal for a framework for National Chemicals Environmental Management (NChEM). The EPHC Chemicals working group (*chaired by Lisa Corbyn, Director General, NSW Department of Environment and Conservation*) was established by Environment Ministers in 2003, as a result of the work by the National Chemical Taskforce (www.ephc.gov.au).

NChEM covers four areas for reform:

1. **Strengthening Environmental Risk Assessment** - clarifying methodologies to assess environmental chemical risks and strengthening consultative mechanisms between national chemical assessment agencies and state and territory environmental regulators so that potential problems are identified and prevented up-front.
2. **Streamlining Environmental Controls** - improving approaches to and consistency in environmental regulation and management of chemicals so that industry can plan for and manage its business with certainty, governments can make better strategic use of resources through practical and joint approaches and the broader community is satisfied that chemicals of environmental concern are appropriately managed.
3. **Informing our Decisions -** improving feedback on environmental impacts of chemicals so that decisions are practical, fit the problem and are informed by on-ground experience.
4. **Prioritising Action** - identifying our highest areas of environmental concern, including a role for the public, so that Environment Ministers can be pro-active and strategically focused.

STAKEHOLDER VIEWS

The NChEM proposals were outlined in a public discussion paper, which was open for comment until 29 September 2006. Written and verbal responses to the discussion paper which relate to this key area of the framework include:

- need to identify the chemicals policy principles and assumptions underlying any discussion of chemical priorities and risks (e.g. role of precautionary principle, substitution principle, burden of proof and extent of producer responsibility).
- appropriate use of science in setting chemical priorities, assessing risks and making risk management decisions (what is "sound science", how much scientific evidence is enough to justify regulatory action, appeal rights regarding risk assessment/management decisions versus policy maker discretion).
- strategies for dealing with poorly understood but important chemical issues e.g. toxicity to the developing and mature nervous/endocrine/immune systems, epigenetics, chemical mixtures
- priority should be given to chemicals that are persistent, bioaccumulative and toxic (PBT) and those that have been banned overseas. If the most significant issues include environmental impacts from therapeutics or food additives, they should not be excluded.
- approaches for tackling the backlog of unassessed existing chemicals in a timely, scientifically sound manner.
- shortage of toxicologists and technical specialists may mean the right expertise is difficult to access.
- what data/information should be publicly available (including labelling of product ingredients).
- mechanisms for strengthening cooperation between health and environment agencies to address potential human health concerns arising through environmental exposures (particularly in relation to chronic, low-level chemical exposures and vulnerable subpopulations such as children).
- cost to business needs to be a factor in establishing priorities.
- priority issues should include strategies for encouraging 'greener' chemistry; addressing chemicals in products (for industrial chemicals), developing the environmental aspects of the Globally Harmonised System for Classification and Labelling (and ensuring its integration with public health, worker health and trade aspects), chemicals affecting children's health, chemicals affecting the recycling of materials, multiple chemical sensitivity.

ATTACHMENT C

Summary of NICNAS and APVMA Chemical Review Programs

The national regulators for industrial chemicals (NICNAS) and agvet chemicals (APVMA) have processes in place to reconsider existing chemicals where new information raises issues of concern, which take into account information and issues raised by stakeholders.

The previous National Chemicals Taskforce, which was set up by the Environment Protection and Heritage Council of Environment Ministers from Australia and New Zealand (EPHC). The Taskforce included nominated representatives from the Health, Primary Industries and Workers safety Ministerial Councils. The Taskforce found that there is a need for greater involvement of the environment arm of government in the determination of the pressing environmental chemical issues of the day, and to set in motion the mechanisms to address them. The Taskforce identified that this process needs to be formalised and structured so that the work complements, supports and informs the existing priority review programs of national assessment agencies. It also noted that broader chemical issues or issues involving groups of chemicals may not be easily addressed under the current systems.

Industrial Chemicals

There were around 38,000 'existing chemicals' listed on the Australian Inventory of Chemical Substances at the time NICNAS was established in 1990. NICNAS introduced the Priority Existing Chemicals (PEC) Review program in 1999 to provide for the screening, declaration and assessment of existing industrial chemicals, on a priority basis.

Under the program any person or organisation[2] with a concern about public health, occupational health and safety, or environmental impacts of an existing industrial chemical may nominate it for assessment. The Director of NICNAS also periodically makes a public call for nominations. The chemicals nominated can be ones that are used on their own, or chemicals that form part of a product (i.e. an ingredient) or industrial process.

After being nominated, chemicals are assessed against a set of criteria covering issues in public health, occupational health and safety, and the environment to determine whether the concerns merit further consideration. Chemicals of concern are then placed on the Candidate List which is used when considering which chemical(s) should be recommended for assessment as PECs. The List consists of a main and a stand-by section. The stand-by section is for those chemicals for which new data are expected which could have an effect on whether the chemical is selected for a PEC review or not. The stand-by section is reviewed annually. At July 2005, there were 53 chemicals listed on the main section of the Candidate List and 12 chemicals listed on the stand-by section.

[2] Includes public, workers, unions, industry groups, public interest groups, and State, Territory and Commonwealth government agencies

Following listing on the Candidate List, the Director of NICNAS may decide that more information is required on a chemical. The Director will seek this information by way of a notice in the Chemical Gazette. The Director will use this information and the information obtained through the screening process to decide whether to recommend that a chemical be declared as a PEC. At 31 January 2006, 20 chemicals from the Candidate List had recently been declared as PECs.

Once a chemical is declared as a PEC, a full or preliminary assessment will be undertaken. A full assessment addresses the hazards, potential exposure and risks posed by a chemical. Preliminary assessments, meanwhile, are tailored to particular aspects of a chemical (e.g. its hazards or exposure) that are the focus of the assessment.

In reviewing a particular chemical, NICNAS uses a number of its consultative mechanisms[3] to discuss and review draft PEC reports/ recommendations prior to finalisation. Final PEC reports are made available to companies introducing chemicals, to people within the workplace, to other Government agencies, and the public. At December 2005, 27 PEC assessment reports (covering 65 chemicals) had been completed since the program commenced in 1991.

The PEC assessment reports contain information on risks to human health and the environment, and recommendations on ways to control and reduce any risks. Safety information sheets containing the main findings and recommendations of a PEC assessment are complied for all PECs, and disseminated to industry, unions and labour councils, and state and territory representatives.

Various activities may be undertaken post-assessment. These include co-operative projects with industry, unions and/or government authorities on such things as communication strategies relating to a particular chemical.

Recommendations from PEC assessment reports can have an important bearing on regulatory action that may be implemented within Australia in the context of protecting the health of workers and the public, and protecting the environment. For instance, they may impact on national occupational exposure standards, hazard classification, health surveillance guidelines, labelling requirements, and the development of codes of practice.

However, it should be noted that as they are only recommendations, there is no requirement that PEC recommendations be taken up. In light of this, NICNAS has been evaluating the uptake of recommendations in a selected number of PEC reports to try to identify factors that may be inhibiting the uptake of recommendations.

PEC assessments are the most well know activity under the NICNAS Existing Chemicals Program. That Program has recently be been reviewed and the Final Report and Recommendations to the Director of NICNAS from the Existing Chemicals Program Review Steering Committee was released in December 2006.

Agricultural and Veterinary Chemicals

When the APVMA was established in 1995, it assumed responsibility for over 5,000 chemical registrations that had been granted under previous arrangements in the States and Territories. In light of this, the APVMA was provided with powers, under the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals (Administration) Act 1992,* to conduct reviews of registered chemicals to ensure they meet current standards of registration and do not pose unacceptable risks to people, the environment or trade.

[3] NICNAS Consultative Committees - Industry Consultative Committee (Commonwealth and Industry), State MOU Group (only state agencies with a MOU with NICNAS - DEH is an observer) and the Community consultative Committee (NICNAS and community reps).

The APVMA's Chemical Review Program reconsiders the registration of agvet chemicals where potential risks to safety and performance have been identified. A review may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical or product. Reviews may be targeted (based on specific aspects of the chemical or product and/or their labels) or may be comprehensive, covering all aspects of the chemical's or product's registration.

At the commencement of the National Registration Scheme the APVMA invited the public, industry, government and academic institutions to nominate existing chemicals for review. Nominated chemicals were assessed against agreed criteria for public health, occupational health and safety, environment, efficacy and trade risks and 79 chemicals listed as priority chemicals for review.

Under the Chemical Review Program the APVMA (in liaison with its advisory agencies within the Department of Health and Ageing, the Department of the Environment and Heritage and partners of the National Registration Scheme ie States and Territories) also continually monitors reports of new information about existing chemical including overseas regulatory actions. In addition chemicals may gain nomination for review on the basis of information received through its Adverse Experience Reporting Program.

A Review Priority Scoring System is utilised to assign a priority to prospective chemical reviews. Nominations are screened, scoped and prioritised based on the urgency or nature of the concern. . For prioritisation, chemicals are scored against the criteria for public health, occupational health and safety, environment, efficacy and trade risks. Chemicals that are chosen for review are placed on the Priority Candidate Review List in priority order[4]. There are currently about 80 chemicals on the Priority List. Chemicals are considered (reviewed) in priority order.

Since the review program began in the mid 1990s, 65 reviews have been commenced of which 34 have been completed. As at 30 June 2006, the Chemical Review Program had 31 ongoing reviews of which 11 were comprehensive reviews and 20 were targeted reviews.

Following the identification of a chemical for review, companies that have registered products and active constituent approvals for the review chemical are notified and required to submit specific data relevant to the review.

Through advertising, the APVMA seeks public submissions on any information or issues associated with the continued registration of the chemical under review. The APVMA also has a number of consultative committees[5], through which it seeks advice and feedback on a number of issues, including chemical review. All submissions of scientific data are evaluated by the APVMA and external advisory agencies (such as the Office of Chemical Safety within the Department of Health and Ageing and the Department of the Environment and Heritage) as appropriate.

[4] The APVMA regularly reviews the priority list through consultation with its advising agencies (such as OCS and DEH) and the State Co-ordinators.

[5] APVMA Consultative Committees – **Registration Liaison Committee (APVMA, State Co-ordinators, DEH, OCS. NSW EPA attend due to control of use responsibilities in NSW**), Industry Liaison Committee (APVMA and Industry reps) and Community Consultative Committee (APVMA and community reps).

Based on an evaluation of the available scientific information, a draft regulatory approach is developed. A draft report and regulatory approach is released for public comment, prior to any final regulatory decisions. Depending on a review's findings, chemicals (and the products containing them) may be:

- confirmed as safe and appropriate for continued registration and use;
- variation to label instructions to limit the situations in which product/s may be used or to modify mandatory risk management instructions; or
- suspended, cancelled or withdrawn from the market.

If, following a review, a product is to be cancelled and withdrawn from the market, suitable timeframes may be established for cancellations and withdrawals to take effect. Timeframes are dependant on the potential hazards and risks. The APVMA has the power to recall product from all levels in the market including the end user if necessary.

PROPOSED NATIONAL FRAMEWORK FOR CHEMICALS ENVIRONMENTAL MANAGEMENT (NChEM)

Priority and Emerging Chemical Issues – Roundtable Workshop, 1 March 2007

Summary of key issues raised

- Environment and community group participants suggested the consultation process could be improved. They suggested the NICNAS Community Engagement Forum as a useful model for interacting effectively with environment and community group representatives, and offered use of networks and contacts of the NICNAS CEF group for distribution of NChEM information. Consultation needs to be designed with stakeholders and sufficiently frequent to maintain knowledge and momentum, but flexible enough to match needs/issues. Can be targeted or more broadly focused depending on need.

- Environment and community groups are keen to see stronger links between environmental exposure to chemicals and their impacts on human health. It was noted that the USA has much greater focus than Australia on environmental health. Members of the Australian community have difficulties in navigating and operating in accordance with government 'silos' e.g. the separation of environment and health portfolios.

- Clearer definition of all terms and principles would be of benefit e.g. what is covered under 'environment protection'. Does it include impacts on people? How are environmental impacts defined or measured?

- Strong support for an integrated and coordinated system for chemicals environmental management, linking closely with APVMA and NICNAS. Given the NICNAS review addressed some similar issues (e.g. adverse impact reporting, NICNAS powers, monitoring), it is important for the Working Group to continue to work closely with NICNAS on such issues to avoid duplication.

- Support for ensuring that existing assessment processes for industrial and agvet chemicals (by NICNAS and the APVMA) are not duplicated, but agreement that coordinated environment agency input to these processes is essential.

- Support for EPHC development of a process to identify and address broader environmental chemical policy issues in a coordinated and inclusive way. Includes making appropriate links with policies being developed and actions being taken by other Ministerial Councils, agencies or groups.

- 'Emerging chemicals' may need to be considered separately from 'existing priority issues'. In terms of emerging issues, it is difficult to focus on what we don't know yet. Could start with what is reported at 'endpoints' of the system e.g. what is in water/sediments, or types of health impacts reported to doctors. Recognise that it is often difficult for doctors to know if there is a problem or not, and generally they do not have time/resources to voluntarily report into a central system.

- Members of the community find it difficult to feed information to governments and are discouraged if there is no response.

- Need monitoring capacity and long term studies to help identify emerging chemical priorities. Could consider establishing a sample bank to look at changing levels of chemicals in the environment over time (e.g. in relation to timing of significant management actions).

- Information needs to be credible and transparent. Its purpose also needs to be clear, as well as the process/pathway within the relevant agency for making use of the information. It was noted that there is generally a lack of information beyond the point of registration of approval.

- Community groups would like to see Australia keeping up with and taking account of international developments e.g. elements of REACH, SAICM, Canadian developments – don't want to 'reinvent' systems and approaches e.g. PBT (persistence, bioaccumulation, toxicity) screening criteria, mechanisms to deal with precaution and uncertainty.

- Noted that the public generally unaware of chemicals management and thinks all chemicals and products have been assessed as 'safe' by governments.

- Examples of possible priority issues raised by participants (e.g. to use to pilot the priority setting system) include:
    - developing a position in relation to the precautionary principle and ecological sustainability, taking into account international action such as the European Union's REACH system of chemicals management.
    - considering incentives (and barriers) for the introduction and use of safer chemicals.
    - Improving focus on chemical sustainability through life cycle analysis
    - developing an effective process for dealing with chemical mixtures as well as individual chemicals.
    - addressing the need for information on impacts of chemicals on Australian plants and animals.
    - addressing issues of chemicals in water (e.g. general environmental contamination, standards for recycling etc).
    - considering how to increase public awareness of risks associated with the use of chemicals, including how to build capacity and understanding in the community and how to get traction on chemical issues in light of overriding concerns of climate change and water.
    - linking environment and health – health issues of concern include Multiple Chemical Sensitivity (MCS), indoor air quality, chronic and long term health impacts.
    - addressing the red tape reduction agenda.
    - specific chemical concerns – atrazine (including assumptions made about use of groundwater and what constitutes an acceptable risk), brominated flame retardants, bisphenol A, phthalates.

Roundtable participants:

Attendees
Mr John Paul (APVMA)
A/Prof Jochen Muller (Entox)
Ms Debra Wilcocks (NICNAS)
Ms Graham Harvey (NICNAS)
Ms Ann Want (ACTA, NTN, NECF)
Dr Alison Bleaney (NTN, NECF)
Dr Liz Hanna (PHA)
Dr Bro Sheffield-Brotherton (NTN, NECF)
Ms Jo Immig via teleconference (NTN, NECF)

EPHC Chemicals working group members
Environment agencies from: the Australian Government, NSW, QLD, WA, VIC, NT, SA; NEPC Service Corporation

Apologies

Dr Peter Holdsworth (Animal Health Alliance)
Ms Paula Mathewson (Croplife)
Mr Leo Hyde (DuPont)
Ms Elizabeth Gibson (RACI)
Mr Adam Wightwick (DPI – VIC)
Ms Julie Smith – (EPC VIC)
Mr Jeff Simpson - (Haztech)
Mr Wayne Thompson (QLD DPI)
Mr Craig Brock (ACCORD)
Ms Elizabeth O'Brien (The LEAD Group, NTN, NECF)
Mr Carlos Santin (PACIA)
Mr John Mollison (DTAE TAS)
Mr David Power (Environment ACT)

Facilitator: Martin Bowles (DECC, NSW)

EPHC CHEMICALS WORKING GROUP
National framework for Chemicals Environmental Management (NCHEM)
ROUNDTABLE

INFORMATION NEEDS
THOUGHT STARTER PAPER
DECEMBER 2006

This thought starter paper focuses on the key area of information feedback and aims to set the scene for determining what information should be fed back into the system (i.e. to national regulators and those involved in chemical management) and where it should be housed and reviewed. An outline of NChEM and key areas is at Attachment A.

Roundtable participants' input is sought on the following information needs that have been identified by the Working Group:

1. Information to enable reporting and evaluation of the effectiveness of NChEM itself (is it delivering the anticipated outcomes?)
2. Adverse impact information - when adverse impacts are observed, is there a system for reporting/capturing them?
3. Environmental risk management controls
    a. what controls are in place?
    b. Are they effective – what outcomes can be observed?
4. Information about the environment
    a. Ambient chemical information?
    b. Sensitive environment specific information?
5. Post assessment/post-registration information
    a. Chemical specific?
    b. Use/location specific?
6. Policy discussion/information flow between national regulators and State and Territory environment agencies
    a. Liaison with NICNAS (the national industrial chemicals regulator)
    b. Liaison with APVMA (the national agvet chemicals regulator)

KEY ISSUES - Proposals for meeting each information need

1. INFORMATION TO ENABLE REPORTING AND EVALUATION OF THE EFFECTIVENESS OF NCHEM (*IS IT DELIVERING THE ANTICIPATED OUTCOMES?*)

This aspect of NChEM is to be considered once the NChEM elements have been agreed. The Working Group will then develop an agreement for heads of reporting, which would be part of the proposed intergovernmental agreement. It is likely that EPHC would report progress to COAG or other intergovernmental forum.

2. Adverse impact information

The EPHC Chemicals Working Group has identified the need for a system to report and capture information about the adverse impacts of chemicals. A few stakeholder submissions also indicated that there is a need for such a system.

Adverse reporting can be separated into the classes of chemicals which are currently regulated in Australia, which are (for the purposes of NChEM), industrial chemicals and agvet chemicals. The following provides a discussion on both categories.

Industrial chemicals

- 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. NICNAS is currently considering its response to this report in the light of stakeholder feedback.
- 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 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, public and government players in both program design and the subsequent 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 confidential, there is a mechanism for information to be publicly accessible
    - the system be comprehensive – i.e. single collection system and not multiple separate information holdings.

Recommendation

1. Note the recommendation of the NICNAS Existing Chemicals Program Review Steering Committee.

2. Request Working Group involvement in whatever mechanism is established to move the recommendation forward.

3. Until such time as the above proposal is progressed by NICNAS, State and Territory environment agencies will agree to provide NICNAS with any information about chemical impacts that they may have, on request

Agvet chemicals

APVMA already has in place an Adverse Experience Reporting Program (AERP) for both agricultural and veterinary chemicals. The AERP for veterinary chemicals has been in place since 1995 and the AERP for agricultural chemicals since 2003. During consultation on the NChEM proposals, some stakeholders identified that these Programs could be improved and some industry stakeholders also raised issues in relation to the cost of developing and implementing such a system.

Whether there is a need to work with the APVMA on refinements to its AERP would be best considered after the feasibility and potential design of an information capture system for industrial chemicals is undertaken by NICNAS in consultation with all stakeholders. This will avoid potential duplication of efforts and should assist in bringing consistency of approach across the chemical management system.

In the interim, APVMA and States/Territories will be encouraged to actively promote the AERP to chemical users (particularly the reporting program for agricultural chemicals, as this is a recent program and is not well known by farmers). In addition, State and Territory government input to the AERP will be improved.

Recommendation

1. Consideration of improvements (from an environment protection perspective) to the APVMA's AERP would not occur until the proposal for an industrial chemicals system has been fully discussed among stakeholders.

2. In the interim, States and Territories agree to report any adverse impacts from agvet chemicals to the APVMA through the existing AERP.

3. Management controls

Industry and other stakeholders need to know what management controls are in place for particular chemicals. All stakeholders need to know whether those controls are achieving the required outcomes. Roundtable members should note this aspect of discussion only relates to management of industrial chemicals. Linking systems

between the Commonwealth and the states and territories for environmental controls are already in place for agvets.

It is proposed that NICNAS could maintain a central database/register of chemicals that includes any NICNAS decisions/recommendations in existence about management controls on those chemicals, covering their full life-cycle e.g. import, manufacture, use, disposal (*e.g. using appropriate annotation of the Australian Inventory of Chemicals Substances or AICS*). A proposal for a surveillance, monitoring and post market reporting system which has been raised as part of the NICNAS Existing Chemicals Program Review could provide a future pathway for environment agencies to report to NICNAS on their implementation of, and the effectiveness of, management controls.

States and Territories could ensure that their existing regulatory information systems are maintained and incorporate relevant chemical control information (*e.g. in NSW information about chemical control orders, pesticides control orders, chemical related legislation (acts and regulations) and chemical related licensing controls is available on the DEC website*).

Recommendation

1. The EPHC chemicals working group will consult and liaise with NICNAS about how AICS could be improved and used as a central database of information. This consultation could occur through consultative mechanisms set up for the existing chemicals review program to review proposals for a surveillance, monitoring and post market reporting system.

2. States and Territories agree to provide information to NICNAS (on request) about management actions they have taken in relation to specific chemicals and any environmental impact information they may have resulting from that action. Environment agencies, in reporting back, could provide advice on any modification of controls needed based on the evidence from chemical use experience in their jurisdiction.

4. Information about the environment

The Australian Government Department of the Environment and Heritage is developing a National Chemical Monitoring Program to improve the reporting of and access to information related to monitoring activities on the use and fate of chemicals in Australia. A key component of this program will be a database with information on the use and fate of chemicals in Australia which would:

- assist chemical regulators to identify emerging chemical issues that require action and consequently contribute to improved chemicals management in Australia
- help verify the effectiveness of policies over the long term through the analysis of data collected over many years
- increase knowledge about the use and fate of chemicals in Australia
- improve access for government chemical regulators to review monitoring data to verify the effectiveness and compliance with decisions related to approval of chemicals
- improve access to monitoring data for other government agencies, industry, research institutions and the general community

- provide a mechanism through which governments can access information to report at the domestic and international level on chemical related issues, which reduces resource requirements for processing such requests
- complement the National Chemicals Information Gateway and the National Chemical Reference Guide.

The database is expected to be available in late 2007. The database could provide a reporting mechanism for NChEM, if appropriate.

Recommendation

1. DEH to work with the EPHC Chemicals Working Group to explore how the reporting and information needs of NCHEM can be incorporated in the database being developed under the National Chemical Monitoring Programme.

5. Post/assessment/post-registration information

The Chemicals Working Group recognises that seeking post/assessment/post registration information about chemical use is a complex issue that poses potential resource and logistical difficulties for chemical users and government agencies. Accordingly, collection of such information must be efficiently targeted to supporting the risk assessment and management processes.

The APVMA and NICNAS risk assessment processes rely on predictive modelling of estimated environmental concentrations. Risk management subsequently relies on a combination of regulatory and voluntary tools to limit environmental impacts of approved chemicals. Monitoring programs designed to obtain post/assessment / post registration information must therefore be targeted to validate risk assessment assumptions and verify that controls are being adequately implemented.

Validation information to support the risk assessment processes should be able to confirm the validity of central assumptions of the risk assessment process, relating to chemical use volumes and applications, disposal routes and environmental fate and impacts. Verification information to support risk management processes should verify whether appropriate controls are being applied.

A monitoring program to provide adequate information to inform the risk assessment and management process is therefore likely to incorporate:

- volumes of chemicals imported, manufactured and stored, to provide a coarse screening tool
- usage patterns, including volumes and types of uses (to identify changes of use which may increase risks)
- disposal and environmental release patterns (including accidental releases)
- reporting of regulatory and voluntary compliance
- environmental concentrations and impacts.

The principles outlined above are applicable to all aspects of post assessment / post registration information gathering.

It is likely that targeted monitoring can be undertaken for a small representative group of chemicals to validate the current NICNAS and APVMA risk assessment and risk management processes. Subsequent information collection should be

targeted and cost-effective, driven by the risk assessment, which will in turn need to be refined to identify risks to be monitored (i.e. which assumptions have the greatest potential to influence the risks associated with a given chemical?).

Recommendation

Chemicals Working Group to establish a working party with representatives from industry, community, NICNAS and APVMA to identify the circumstances in which such information would be of benefit, how it could be best obtained and used, noting the need for cost-effective systems.

6. Policy discussion/information flow between national regulators and State and Territory agencies

Industrial Chemicals

The Chemicals Working Group is aware that better coordination and information exchange between NICNAS and States and Territories was identified as an issue needing action in the NICNAS Existing Chemicals Program Review. The Working Group concurs with this view. There is a need for better information flow between State and Territory environment agencies and NICNAS both on specific chemicals and their assessment and at the more general policy level.

Specific proposals for modifications to the way environment agencies contribute to the assessment of individual chemicals are set out in the Discussion Paper and are predominantly captured in key area one – improving environmental risk assessments. Stakeholders have raised no objections and the Working Group is progressing options and suggestions with NICNAS and DEH. These discussions are to consider cost and resource efficient mechanisms, for example whether better use can be made of the existing NICNAS MOU group or whether separate regular dialogue is needed with environment agencies.

Recommendation

The Chemicals Working Group continue discussions with NICNAS to identify an agreed approach for better coordination and cooperation between State and Territory environment agencies and NICNAS on industrial chemical management issues, noting that the Existing Chemicals Program Review Steering Committee has recommended to NICNAS it explore with states and territories

Agvet Chemicals

The APVMA already consults regularly with States and Territories via its Registration Liaison Committee (RLC), although environment agency input via this process is limited. The Chemicals Working Group notes that the APVMA is considering how best to consult more broadly with state and territory environment and health agencies and notes its current preference that: no new consultative committees be established; and that the opportunities afforded by existing committee structures and membership be better utilised.

The Chemicals Working Group agrees that bureaucratic structures should be kept to the minimum required for effective consultation and information flow/exchange. As

all stakeholders support better coordination among government agencies, these proposals will be progressed and implemented as soon as practicable.

Recommendation

The Working Group continue discussions with APVMA to:

- identify an agreed approach for better coordination and cooperation between State and Territory environment agencies and APVMA on agvet chemical management issues. These discussions to consider, in the first instance, the feasibility of better environment agency

SUBMITTING COMMENTS ON THOUGHT STARTER

Please submit your comments via e-mail to: Lisa Nardi at nchem.roundtables@environment.nsw.gov.au. Comments will be circulated to all roundtable members for their information so that informed discussion of all views can take place.

If you would like to discuss details of your comments with your EPHC Chemicals working group member in your State or Territory, contacts are provided below:

Contact	Telephone	Email
Australian Government		
Mr Lee Eeles	(02) 6274 1427	Lee.Eeles@deh.gov.au
New South Wales		
Ms Liz Moore/ Dr Jane Mallen-Cooper Lisa Nardi (NChEM project coordinator)	(02) 9995 5903	Liz.Moore@environment.nsw.gov.au Jane.MallenCooper@environment.nsw.gov.au Lisa.nardi@environment.nsw.gov.au
Victoria		
Dr. Barry Warwick	(03) 8458 2340	barry.warwick@epa.vic.gov.au
Queensland		
Dr Faiz Khan	(07) 3227 7349	faiz.khan@epa.qld.gov.au
South Australia		
Mr David Duncan	(08) 8204 2094	david.duncan@state.sa.gov.au
Western Australia		
Mr Doug Hide	(08) 6467 5378	doug.hide@environment.wa.gov.au
Tasmania		
Mr John Mollison	(03) 6233 6270	John.Mollison@environment.tas.gov.au
Australian Capital Territory		
Mr David Power	(02) 6207 5311	david.power@act.gov.au
Northern Territory		
Mr Michael Lawton	(08) 8924 4031	Michael.Lawton@nt.gov.au

Attachment A

STAKEHOLDER VIEWS

The proposals for NChEM were provided in a public discussion paper, which was available for public comment until 29 September 2006. Responses which relate to this key area of the framework include:

- how would NChEM improve mechanisms for feeding environmental agency views/experiences into the national assessment process without adding unjustified complexity, expense and delays?
- how much of the inputs into assessments for existing chemicals should be "hard data" supplied by industry as opposed to "soft" estimates that are computer modelled or judged appropriate by experienced risk assessors?
- if information is required from industry (e.g. toxicity or use data) for existing chemicals, what information should be provided and what should trigger this requirement (e.g. human exposures likely, lack of data versus evidence of harm, evidence of failed existing regulatory controls)?
- use data may be difficult to obtain for agvets, as registrants have no direct links with end users (use wholesalers and marketers).
- how do privacy and commercial in confidence requirements affect data gathering and feedback systems?
- should data requirements for new chemicals be expanded?
- what are cost-effective mechanisms for generating and sharing environment/health impact and exposure information for chemicals and who should pay for this?

PROPOSED NATIONAL FRAMEWORK FOR CHEMICALS ENVIRONMENTAL MANAGEMENT (NChEM)

Information Needs – Roundtable Workshop

2 March 2007

Summary of key issues raised

- Improving information flow and communication among all relevant governments and agencies strongly supported by all participants e.g. useful to feed State and Territory monitoring/adverse experience information into the assessment systems of NICNAS and APVMA.
- Stakeholders keen to see the EPHC Chemicals Working Group link with and contribute to related work being carried out by other agencies, rather than duplicate work e.g. all stakeholders support the Working Group providing input to the proposed NICNAS scoping study on the feasibility of a nationally co-ordinated system of surveillance, monitoring and post market reporting for industrial chemicals.
- There was also support for the possible refinement of existing information capture/storage systems, such as the Adverse Experience Reporting Programs for agricultural and veterinary chemicals established by the APVMA, once all stakeholders have clearly identified what they think such a system should cover and how it might operate most effectively (e.g. through the work with NICNAS).
- The NICNAS Australian Inventory of Chemical Substances (AICS) was generally viewed as a good system to incorporate information on environmental management controls and for it to operate as a 'one stop shop' for industry by incorporating all regulatory requirements (environment, health, OH&S). A potential impact on confidentiality listing was raised as an issue that needs consideration *(i.e. concern from environment and community group representatives that more chemical manufacturers and re-formulators might seek confidential listing)*.
- Environmental monitoring was seen as important, including to check that Australia is meeting its international commitments and to provide input to priority-setting processes. There was wide support for the Australian Government Department of Environment and Water Resources' proposals (at the costing/feasibility stage) for a national monitoring database and a sample bank. Costs of data analysis are high and need to be considered upfront in any sample bank model, as lack of resources for periodic analysis could impact on the ongoing usefulness of a sample bank.
- Need to ensure processes are in place to indicate the validity of information being stored in databases or used in adverse reporting schemes. Also need to consider issues such as ability of community members and other stakeholders to access such information (including cost of access).
- Health agency/system linkages with environmental monitoring systems need to be considered. Need to better understand inter-relationships between environment and health. Also need to note that current systems and structures do not deal well with multiple chemicals/chemical mixtures and non-acute impacts such as endocrine disruption.

- Actions outlined in Roundtable thought-starter paper generally supported as good start for information improvements.

Roundtable participants:

Mr John Paul (APVMA)
Mr Nick Miller (NICNAS)
Mr Bob Graf (NICNAS)
Ms Wafa El-Adhami (Office of Chemical Safety)
Mr Craig Brock (ACCORD)
Ms Elizabeth O'Brien (The LEAD Group, NTN, NECF)
Ms Ann Want (ACTA, NTN, NECF)
Dr Alison Bleaney (NTN, NECF)
Dr Liz Hanna (PHA)
Ms Margaret Donnan (PACIA)
Dr Mariann Lloyd-Smith (partial attendance via phone (NTN, IPEN, NECF)

EPHC Chemicals working group members
(ENVIRONMENT AGENCIES FROM: Australian Government, NSW, QLD, WA, VIC, NT, SA)
NEPC Service Corporation

Apologies
Dr Peter Holdsworth (Animal Health Alliance)
Ms Paula Mathewson (Croplife)
Mr Leo Hyde (DuPont)
Ms Elizabeth Gibson (RACI)
Mr Adam Wightwick (DPI VIC)
Ms Julie Smith (EPC VIC)
Mr Jeff Simpson (Haztech)
Mr Wayne Thompson (QLD DPI)
Mr John Mollison (DTAE TAS)
Mr David Power (Environment ACT)

Facilitator: Peter Marczan (DECC NSW)