PUBLIC HEALTH ASSOCIATION
of Australia Inc

Chemicals and Plastics Regulation

Productivity Commission Issues Paper

Public Health Association of Australia Submission

Background – The Public Heath Association of Australia

PHAA has branches in every state and territory. Membership of around 1500 individuals spans the health spectrum and over 40 public health related occupations are represented. PHAA has thirteen Special Interest Groups for members to exchange information and to develop policy positions and papers across range of issues relevant to the health of Australians. As PHAA has a national and multidisciplinary perspective on public health issues it is able to make a major contribution to the public health debate in Australia. Members promote public health through representation on government boards, committees and other decision-making bodies.

(More information on the PHAA *http://www.phaa.net.au/aboutUs.php*

The arguments presented in the submissions of the NICNAS CEF and the ACTU are endorsed, with the exception that the PHAA is not philosophically opposed to centralising regulation **if** the outcome was to achieve greater rigour and reduce the gaps by introducing a simpler process that had national consistency, and was workable. Focus of this submission is on human health.

The chemical - human interface

The PHAA has been noting with interest the recent developments on Chemicals Management in Australia. Increasing reliance on chemicals over recent decades, in Australia and globally, entails that chemicals are now ubiquitous in our environment. The principal concern for PHAA is the health impact of exposure.

Chemical usage in industrialised economies expanded dramatically in the second half of the last century. Over 100,000 chemicals are now registered for use in the USA, and Europe. Australia has almost 40,000 industrial chemicals registered. Only 183 of these have been reportedly reviewed for their effects on human health or the environment, and only 44% of the chemicals classified as high priority have undergone assessment during the 17 years of Regulation. This situation for chemicals used in agriculture is similar. Since identifying 600 possible chemicals of concern 12 years ago, the Australian Pesticides and Veterinary Medicines Authority has completed 59 reviews, with 37 chemicals still being investigated, according to a recent report published in the SMH. NICNAS has publicly revealed the gap in assessments, however accessing exact figures relevant to the APVMA has proven difficult, when direct requests for information have not received answers.

This unwieldy backlog of untested chemicals is now emerging as a global issue, and the workload for regulators is compounded by the need to assess the many hundreds of applications for new chemicals every year. The chemical assessment process does not involve product testing by regulatory authorities, rather, relies heavily on reviewing the data provided by the manufacturer.

Another plank in Australia's safety regime is the chemical regulatory system itself, but weaknesses are inherent in the present system. Four national regulatory authorities are responsible for different chemicals based upon their intended usage. For example, the Australian Pesticide and Veterinary Medicine Authority (APVMA) registers pesticides that can be sold in Australia, and stipulates precise usage conditions according to specific guidelines, such as the concentration and type of crop. The APVMA publishes guidelines for the spray nozzle characteristics and meteorological conditions allowable for their application,[1] but these guidelines are not always followed. Their jurisdiction stops at the point of sale. Various State and Territory departments are then responsible for enuring safe transport of chemicals, their correct application and usage, and ultimate fate and disposal. NICNAS currently does not have the same powers as the APVMA in setting guidelines for usage. The regulatory system is exceedingly complex, with differing legislation across jurisdictions, making the system cumbersome and difficult for people and companies to comply. In most states, no training is required to purchase or apply highly toxic chemicals, and in some states, compliance monitoring for correct application is negligible. Breaches do exist [2], PHAA is concerned that such breaches are not being identified, so such practice cannot be monitored.

The 2002 Australian Academy of Technological Sciences and Engineering report called for improvements in chemical regulation, arguing the present regulatory framework is fragmented and incomplete. This Radcliffe Report noted the inconsistent infrastructure operating across Australia was placing Australians at risk. It attributed Australia's inability to determine past and current trends in application or usage of chemicals to the lack of a detailed surveillance system. [3]. No data exists on the quantities of the active ingredient or the formulated products that are applied [4], nor is there any mapping data on where agricultural chemicals are applied. National Pollutants Inventory details industrial chemicals, yet this also is incomplete, and therefore inbuilt inaccuracies limit its utility as a useful database.

The European Union and the USA are instituting regimes to minimise harmful chemical exposure, and to monitor chemical application, usage and disposal, and to measure the chemical burden amongst the population. Australia has yet to introduce such schemes. This leaves Australia in the situation where large volumes of chemicals are being used, and there will be situations where safety guidelines are not being followed, resulting in hazardous exposure levels. The lack of intelligence about where these breaches are occurring, or any measurement of health impacts means the size and nature of this problem is unknown.

Absence of monitoring and surveillance data is worrisome. The PHAA is concerned that regulators are required to make assessments of safety without knowledge of WHAT CHEMICALS, are used WHERE, or HOW, in WHAT VOLUMES, or indeed their ULTIMATE FATE or disposal. Secondly, communities have a right to know what chemicals exist in their local environment, so they may make informed decisions about where they chose to live, work and play. Thirdly, this lack of data hampers appropriate health care management of people exposed through occupation, domestic or even recreational activities, and inhibits the capacity to demonstrate whether links exist – or not. The absence of such information restricts research and serves to fuel community angst.

Chemical regulation exists for one purpose, and one purpose alone, and that is to ensure safety, that is, to protect human health and the environment from risks associated with chemical exposures. The manner in which such a system functions ought be designed to be fair to industry by not introducing advantages or disadvantages between industries or companies, other than those based on the potential impact of the chemicals manufactured or used by that industry or company.

The reasons that chemical regulation must prioritise the protection of human health are compelling. An emerging body of evidence now attributes a range of health conditions to chemical exposures[5-8]. Scientifically valid evidence has been slow to amass, relative to other direct cause-effect studies, due largely to the inappropriateness of conducting randomised control studies involving humans and chemicals. The USA EPA has reversed a decision to now allow the use of human subjects in exposure studies, including paying subjects to drink chemicals [9-11]. However whilst the level of evidence may be rigorous, for ethical reasons this practice is not endorsed by other OECD countries. In our daily lives we are exposed to thousands of chemicals throughout our lifetime. Many exposures are simultaneous, and in mixtures, and some exposures occur in utero, such that our exposures as adults impacts upon our children[12]. It has therefore been very difficult against this background, to categorically prove that exposure to X causes Y.

Despite these challenges, evidence linking exposures to ill-health are emerging through epidemiological studies. Demonstrated links have been shown to immune impairment, suggesting that exposures are contributing to the observed increases in allergenicity, cancers, diabetes, in addition to the solid evidence for neurobehavioral conditions resulting from chemical exposures[13-19].

Health vs profits: Must it be an either /or decision?

The PHAA recognises industry complaints about the regulatory burden placed upon them, and fully concords with calls for a regulatory system that is efficient AND effective, and which does not add unnecessary burden. The definition of what constitutes 'unnecessary', or 'excessive' burden becomes the critical issue in any debate on *Rethinking* of *Regulation.*

The nature of a regulatory system is to shift any burden arising from chemicals away from community members (and the environment) to industry. The cost impost of industry taking up this burden eventually is passed back to the community. The Australian public should not be placed at any additional risk.

In 2004, the United States House Of Representatives Committee On Government Reform — Minority Staff Special Investigations Division presented a case study to demonstrate ….

> "that the Administration, at the request of the U.S. chemical industry, mounted a campaign to block the efforts of the European Union to regulate chemical companies……
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> At the urging of the chemical industry, however, the Bush Administration reversed this policy and actively opposed European Union efforts to improve the regulatory system for chemicals. The Administration's opposition to the initiative was extensive, involving multiple government agencies, cables from Secretary of State Colin Powell, and an international lobbying strategy (… *which included Australia*…) closely coordinated with representatives from industry. Ultimately, the European Union adopted numerous changes proposed by the Administration."[20]

The full report presents a damning indictment of a government capitulating to industry pressure. The PHAA is external to the chemical regulation process, and it is not in a position to verify these actions, nor to presume the motives of the Australian Chemical lobby. It does however note the concerns raised by the American Public Health Association and the Union of Concerned Scientists to the impact the chemical industry had on swaying the US government to intervene in the European chemical regulation, primarily to benefit US chemical trade. These and other groups have lodged strong opposition to strategies adopted by the Bush Administration, at the behest of

chemical lobby groups, which served to diminish global attempts to improve chemical safety. Australia was, according to the report, also targeted in this campaign. The PHAA is concerned about the potential for such a campaign to distort the perspectives of policy makers and is therefore wary of ramifications for "easing the regulatory burden" for the Australian chemical industry if potential impacts of human health are overlooked.

Earlier this year, Prof Tyrone Hayes an international expert, presented his findings to an audience of regulators invited by the APVMA. His presentation demonstrated the body of research investigating that multiple negative impacts of atrazine were found in studies (approximately 30), that were NOT funded by the manufacturer, whereas a small handful that had received such funding found nil or limited effect. For his efforts to demonstrate this, Prof Hayes has been the subject of a smear campaign in the U.S. Disappointingly, the APVMA sought to publicize that negative press (in an interview to the Canberra Times), rather than pay heed to the scientific evidence. Such examples do not elicit confidence of independence necessary for regulatory assessment process.

Industry has access to vast resources and influence. These can carry significant weight, and enables industry to devote considerable efforts to presenting persuasive arguments as to supposed 'national benefit' for more profitable trade. The voice of population health and the environment is poor by comparison. These interests are most commonly represented by volunteer organisations, with people working in their personal time. By definition, then, their submissions will be few, and most probably, limited in scope. But it must be noted that the PHAA submission is representing the health of the Australian population.

It falls to the health sector to alleviate the symptoms associated with exposure (known or unknown), and care for the sick, including the sad task of advising people that their incapacity may be permanent or fatal. The Australian public assume that their regulatory authorities ARE protecting their health, that products on the market ARE safe to use, AND have been tested. And furthermore, Australians expect that the health sector can identify, manage and hopefully cure any ailment that befalls them. All these assumptions can be questioned, in the light that none of these systems are perfect. Alterations to chemical regulation must incorporate the fact that Australia's past history of relative "collective success" is a function of their interconnectedness.

The regulatory system is indeed a SYSTEM. Changes to one component will impact on efficacy throughout the entire system, and the inherent fragility can emerge if one pillar is allowed to crumble. Protection of human health from the harmful effects of chemical exposure needs a regulatory system that is primarily designed to protect human health and the environment. It must have several vital features, including:

- being comprehensible and workable
- having the capacity to identify and remove hazardous chemicals from the market,
- working to promote moves towards safer chemistry
- working to actively reduce reliance on chemicals by assisting government to advance practices that minimize chemicals usage,
- encouraging and facilitating compliance with
    - safe manufacturing processes,
    - safe transport,

  - safe usage and
  - safe disposal,
- recording the movement of chemicals throughout the community/environment,
  - so that mishap can be tracked, and allow research and health systems to identify negative outcomes arising from chemicals.
  - To enable the community "to know' their risks

Specific Points:

Nanotechnology is an emerging concern. Whilst there is bountiful funding available to promote its expansion, in repose to enticing promises of wonderful products, including health merits, the negative impacts have received scant attention. The history of science is littered with disastrous examples of premature embracing of untested technology. Notably the devastation usually does not fall upon those who stand to benefit. Little is known about the potential harms, nor of how to rid the world once nano particles are released, and research funding has been predictably insignificant, despite the cohesive calls from the health and research communities across the globe. Some early research is beginning to show harmful effects.[21-23]

The PHAA urges prompt consideration to introducing regulation, and promoting research into the potential harms.

Multiple Chemical Sensitivity is also increasing in the community. This area is also little researched, but is known to emerge in response to exposure. A precautionary approach to chemical management is needed to prevent this disorder spreading further.

Industry Self Regulation has proven ineffective in many cases as observed by the trend for chemical industries to relocate to developing countries with lax regulation, and disastrous results, eg Bhopal. The PHAA does not support moves to allow such relaxing of regulatory frameworks within Australia.

Concluding Remarks:

The PHAA recognises and applauds the efforts made by diligent regulatory agencies and their staff in Australia, and also efforts of members of the chemicals and plastics industry which have been directed towards supporting a safe chemicals management system. Australia benefits from the numerous examples where a relationship of respect exists between the sectors to achieve workable solutions and sound decisions that are vital to safe chemicals management. The PHAA acknowledges that the present regulatory system in Australia is cumbersome and overtly complex, and welcomes a redesigning of the system to improve its effectiveness and efficiently, and perhaps more importantly, by making it easier for industry to be good corporate citizens.

The PHAA stresses that the existing system has many benefits, but is also wrought with failings which increase the risks of hazardous exposure, and therefore urges that changes provide additional protection to human health, rather than lessen that protection.

The PHAA calls for the Productivity Commission to recognise that the **primary purpose** of chemical regulation is to protect human health and the environment. Bearing this in mind, the design of a regulatory system should pose the question at every juncture "Which decision maximises human health protection"?

Maximising profits, whilst being ultimately desirable is not necessarily mutually exclusive to safety. It ought be a secondary consideration for a chemical management regime. The PHAA urges that a health impact assessment be conducted to evaluate potential impacts of any changes introduced to the regulation of the chemicals and plastics industry in Australia.

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