



Australian Government
Department of Health and Ageing

Commissioner Michael Woods
Chemicals and Plastics Regulation Study
Productivity Commission
Locked Bag 2, Collins Street East
Melbourne VIC 8003

Dear Commissioner Woods

Submission to the Draft PC Study into Chemicals and Plastics Regulation

Following our recent phone discussions with Paul Belin, I am pleased to formally provide the Department's comments on the Draft PC Study. I apologise for the delay in responding but a number of the draft recommendations have required extensive policy consideration.

We agree that it is vital that Australia has a nationally consistent regulatory and policy framework that delivers appropriate health, safety and environmental (HS&E) protection. It is only through the sound management of chemicals in protecting human health and our environment that economies are able to enjoy the full benefits that the use of chemicals can offer.

The role of government is to provide a policy and regulatory framework to ensure the safe and sustainable use of chemicals balanced against the need to deliver a business operating environment which stimulates growth, sustainability, productivity, innovation and trade.

As such, the Department particularly welcomes the articulation within the Draft Study of the governance framework that enhances national uniformity by addressing regulatory issues at four levels: (a) policy development and regime oversight; (b) assessment of hazards and risks; (c) risk management standard setting; and (d) administration and enforcement of chemical management tools.

Whilst the draft Study confirms that the chemicals regulatory framework is rightly focussed on the pre-market health, safety and environmental regulation of chemicals, with post market surveillance capability, we also note that efficient and effective regulation is delivered only when each of these four levels operate in a responsive and coordinated manner.

The Department's comments (Attachment 1) are limited to those recommendations that relate to the role of the Commonwealth Health portfolio in regulating chemicals and plastics and specifically our mandate to deliver best health and safety outcomes for Australians. I note that we are formulating more detailed consideration of the draft recommendation 5.1 calling for a new model for drugs and poisons scheduling. The Department is considering the risks associated with this recommendation as the PC proposal differs significantly from the Australian Health Ministers' Conference (AHMC) model previously agreed. We hope to provide additional details and possible options for consideration by the PC as soon as

possible; noting that poisons scheduling implementation is a state and territory matter with policy governance under AHMC/National Coordinating Committee for Therapeutic Products (NCCTP).

In addition to the specific issues identified under the draft recommendations, given that the implementation of chemical risk management measures is predominantly a state and territory function, I note that the proposed increased frequency of COAG meeting, coupled with the proposed new overarching governance body at Ministerial Council level, offers an opportunity for eliminating inconsistencies in the application of chemicals regulations both in the short term and importantly as part of a sustained commitment to chemicals regulation reform.

I would be pleased to discuss our comments further with you.

Yours sincerely

Cath Halbert
First Assistant Secretary
Office of Health Protection
June 2008

ATTACHMENT 1: DOHA COMMENT ON DRAFT PC STUDY RECOMMENDATIONS

National policy formulation and system governance

***Draft Recommendation 3.1:** Subsequent to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation having completed its reference, the Commonwealth, states and territories should establish, under the Australian Health Ministers' Conference, a [officials] Standing Committee on Chemicals, comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would: provide an ongoing forum for assessing:- the consistency of chemicals-specific policy settings across the various areas of concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security;- the effectiveness and efficiency of the overall chemicals-specific regulatory system address emerging issues, such as nanotechnology oversee the consistent application of chemicals hazard and risk-assessment methodologies make recommendations for specific actions by individual ministerial councils.*

Comment: The articulation of the national regulatory framework as operating at four levels has highlighted the need for an overarching governance structure at the Ministerial Council level. Given that the majority of concerns over chemical use are health and/or environmental in nature and that the bulk of the regulatory framework is located within the Health portfolio the selection of AHMC to undertake the coordinating governance role is seen as appropriate. Whilst supporting the recommendation, it is noted that there is a need for further clarification as to the arrangements for interaction between all the relevant Ministerial Councils and the Standing Committee on Chemicals under AHMC.

National hazard and risk assessment

***Draft Recommendation 4.1:** An objective of NICNAS should be to maximise net community benefit, and its assessment requirements and outcomes should be supported by analysis of the associated costs and benefits.*

Comment: DoHA suggests that further clarification as to the intent of this recommendation be provided. A further suggestion would be to include establishing statutory timeframes in dealing with NICNAS recommendations within the Commonwealth's risk management response framework.

The ICNA Act compels notification and assessment on the introducer of chemicals and does not control downstream regulation or chemical management actions. NICNAS makes recommendations to other bodies or applies standards frameworks/criteria established by other bodies, (eg workplace classifications for hazardous substances). It is these risk management standard setting bodies who are responsible for risk management decisions.

As such the NICNAS risk assessment process itself is not subject to the need for a regulatory impact statement (RIS), if any cost benefit assessment was required, this would be the responsibility of the agency that makes the risk management decision rather than NICNAS.

When NICNAS changes aspects of its operations and other policy related matters these would be routinely subjected to cost-benefit assessment as required.

The current regulatory system only works effectively when the risk management agencies and standard setting bodies respond in a timely manner to the NICNAS risk assessment recommendations. To ensure regulatory efficiency in the consideration of NICNAS recommendations, risk management agencies should be compelled to consider recommendations within statutory timeframes.

***Draft recommendation 4.2:** The role of NICNAS should be limited to the scientific assessment of the hazards and risks of industrial chemicals.*

Comment: NICNAS is a regulatory scheme responsible for operating the introduction of new chemicals into Australia as well as reviewing the risk posed by chemicals already in use (existing chemicals). The PC recommendation as it stands would effectively remove the regulatory role for the new chemicals program. Given that NICNAS is already a light touch regulator, this would in effect remove all controls over the introduction of new chemicals with potential risk to health and the environment. Further, if NICNAS was to cease the new chemicals regulation, another (presumably Commonwealth) body would need to be created to carry out this function with attendant costs and increased regulatory complexity.

DoHA does not support the PC view to limit NICNAS scope to only risk assessment.

Regarding the PC view not to enhance the current powers of NICNAS to include specific new powers to ban and restrict chemicals as raised in the 2006 NICNAS Review of Existing Chemicals Assessment Program, DoHA support this view preferring to preserve the four levels of regulatory operations with a separation of risk management standard setting from NICNAS. In doing so, we also recognise that the efficiency and effectiveness of this framework depends on the timely consideration of chemicals risk, as identified by NICNAS, so as to establish an appropriate risk management approach so as to achieve safe use.

***Draft Recommendation 4.3** A technical advisory committee should be established within NICNAS, as a statutory requirement*

Comment: DoHA supports the recommendation. To ensure robust consideration of human health and environmental protection, the technical advisory committee would need to be independent and expert-based.

Draft Recommendation 4.4 *NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that: screens all existing chemicals to develop a list of high priority chemicals for assessment; makes greater use of simulation techniques based on the hazards of chemical analogues; urgently reviews the scope for recognising the assessment schemes of a range of other countries as 'approved foreign schemes'. Priorities should be the schemes operated by Canada, the European Union and the United States. The incremental cost of this program, which is in the broader public interest, should be met from budget funding.*

Comment. DoHA supports, in principle, the accelerated implementation of the reforms noting however, any change to the cost recovery arrangements would first need to be examined via a cost-recovery review/CRIS process. If cost recovery remains status quo, acceleration will have resource implications for the NICNAS budget.

An initial action will be to implement a program to accelerate screening of NICNAS Existing chemicals, through a focused acceleration that will utilise 16,000 Canadian screening assessments as appropriate and hence significantly address 40% of the chemicals listed on the NICNAS inventory.

Draft recommendations 4.5, 4.6: APVMA

Comment. DoHA is only indirectly involved as it provides human health risk assessments to APVMA.

Public Health

Draft recommendation 5.1: *The Australian Health Ministers' Conference should agree to separate responsibility for the scheduling and regulation of poisons from that of drugs. An intergovernmental agreement should be prepared between the Commonwealth, state and territory governments to:-establish a Poisons Standing Committee under the Australian Health Ministers' Advisory Council to design the poisons schedules and the attached regulatory controls, and oversee the poisons regulatory process at all levels of government -establish a Poisons Scheduling Committee of science experts under the Poisons Standing Committee, appointed by the Ministerial Council on the basis of their knowledge and experience, rather than on who they represent, to make decisions about the appropriate scheduling of poisons.*

Comment. DoHA does not support Draft Recommendation 5.1 as it currently stands noting it adds regulatory layers and hence regulatory burden and cost. DoHA is considering the risks associated with this recommendation as the PC proposal differs significantly from the AHMC models previously agreed. The AHMC poisons scheduling model built on the Galbally Review scheduling recommendation and was influenced by the need at that time for an Australia New Zealand scheduling model for medicines.

Draft Recommendation 5.2: State and territory governments should: uniformly adopt regulatory controls through either a template or model approach, adopt poisons scheduling decisions made at the national level directly by reference, report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference. **And**

Draft Recommendation 5.3: State and territory governments should exempt authorised users of poisons in the industrial environment from poisons controls. Such users should be regulated by appropriate workplace substances regulations.

Comment. DoHA is only indirectly involved, through membership of NCCTG and NDPSC, but supports efforts for national consistency in drugs and poisons scheduling and in the application of the poisons schedule for the domestic use of chemicals.

Draft Recommendation 5.4: The Ministerial Council for Consumer Affairs should initiate the development of a broadly-based hazard identification system, based on a clearing house approach, in line with the recommendations of the Productivity Commission's 2006 report on consumer product safety (PC 2006, recommendation 9.1). It should be coordinated by the Australian Competition and Consumer Commission, and take account of health and safety issues around chemicals released from consumer articles.

Comment. DoHA is only indirectly involved through the International Health Regulations obligations but supports consumer product safety initiatives.

Draft Recommendation 5.5:The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systemic research program to identify and deal with the risks of chemicals in consumer articles.

Comment. DoHA is only indirectly involved through the International Health Regulations obligations but supports consumer product safety initiatives

Draft Recommendation 5.6 The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.

Comment. DoHA supports the status quo in terms of the regulatory coverage of NICNAS. NICNAS should remain as the regulator of cosmetics in terms of the scientific risk assessment of the individual cosmetic chemicals. Clarification is sought on which elements of the cosmetic standards would transfer to ACCC. Alternatively, the Cosmetic Standard may need legislative amendment to better clarify the NICNAS scope.

Draft Recommendation 5.7 *The Australian Government should add 'deemed-to-comply' provisions to the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (Cwlth) for fully-imported cosmetic products that meet the cosmetic labelling requirements of specified countries that have labelling requirements that produce sufficiently comparable policy outcomes.*

Comment. DoHA does not support the Draft Recommendation. Australia has a stringent labelling code for cosmetics that provides ingredient information to the consumer to facilitate informed choice. This proposal has the potential to lower Australia's public health protection standards.

Draft Recommendation 5.8: *The Ministerial Council on Drug Strategy should develop illicit drug precursor regulations for adoption by reference by all jurisdictions. The associated risk-based schedule of chemicals and apparatus subject to the regulations should be maintained by a committee of experts overseen by the Ministerial Council, and also be adopted by reference in each jurisdiction.*

Comment. DoHA is only indirectly involved, as the provider of national licenses and permits, but supports efforts for national consistency in the application of precursor chemical controls.

Draft Recommendation 5.9: *Maximum residue limits set by the APVMA, which take account of dietary impacts using methods agreed with Food Standards Australia New Zealand (FSANZ) and the Australian Government Department of Health and Ageing, should be automatically incorporated into the Australia New Zealand Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a cost-benefit analysis and be reported publicly.*

Comment. DoHA believes that the recommendation can be explored and would require a FSANZ Act amendment. It should be noted that implementing this recommendation will also require the agreement of the States and Territories and potentially New Zealand, as the COAG Food Regulation Agreement will also need to be amended.

Workplace Safety

Draft Recommendation 6.2 *The Commonwealth, state and territory governments should replace the existing systems of regulation of workplace hazardous substances and dangerous goods with a single system of regulations for the classification, labeling, provision of material safety data sheets and risk assessment for all workplace hazardous chemicals. The new system should be based on the Globally Harmonised System of Classification and Labeling of Chemicals (GHS).*

Australia should not implement the new system until our major trading partners have implemented the GHS. In this context, the European Union has announced that it intends to move to a GHS-based system in 2015.

Comment. DoHA supports Draft Recommendation 6.2. DoHA is currently undertaking a situational analysis of the application of the GHS system to the Poisons Scheduling system for domestic chemicals. The current timeline for this analysis is to provide a recommendation to the NCCTG and AHMAC in late 2009/early 2010.

Analysis to date has established that GHS provides an improved hazard classification system for chemicals. The PC recommendation of implementation of 2015 is appropriate as internationally many countries are yet to establish to what extent they will implement GHS.

Draft Recommendation 6.4. *In light of the agreement by the Workplace Relations Ministers' Council (the Council) to replace the Australian Safety and Compensation Council with a new and independent national body, the Commission recommends: the new body be statutorily independent and made up of five to nine members appointed by the Commonwealth Minister on the basis of their qualifications and experience, and be constituted to reflect the broader public interest, rather than represent the interests of particular stakeholders the appointments by the Commonwealth Minister be approved by the Council the new body have the ability to appoint advisory bodies, noting the importance of consulting with employers, unions and all jurisdictions the Council be required to formally approve national standards and codes of practice prepared by the independent national body. Agreement by all jurisdictions to adopt, without variation, the standards and codes approved by the Council.*

Comment. Whilst DoHA is not directly involved in this recommendation, it is currently an ASCC recognised competent Authority to set hazard classification for workplace hazardous substances using the ASCC classification criteria (OCS does this activity for pesticides, and NICNAS does this for industrial chemicals). Any new Authority would need to confirm ongoing arrangement to ensure both NICNAS and OCS operate a one stop shop in applying workplace hazard classification to pesticides and chemicals as part of their risk assessment processes, thus maintaining efficiency and cost savings.

Environment protection

Draft Recommendation 8.1 The Environment Protection and Heritage Council (EPHC) Chemicals Working Group should continue to assess the need for a national framework for the management of chemicals in the environment. If this work demonstrates that such a framework would improve effectiveness and efficiency, the Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body reporting to the EPHC. This body would develop standards for the environmental risk management of chemicals that the states and territories

would adopt by reference, and have the power to ban or phase out chemicals, subject to appropriate cost-benefit analysis. Members of the environmental risk management standard setting body should be appointed based on their qualifications and experience. The body should be constituted to reflect the broader public interest and have the ability to appoint advisory bodies as necessary.

Comment. DoHA supports Draft Recommendation 8.1. NICNAS is responsible for assessing the risks posed by chemicals to human health and environment and for making recommendations to relevant bodies on how to manage these risks. A nationally consistent system for environmental protection would enhance the national regulatory framework.