



Public Health Association
AUSTRALIA

Public Health Association of Australia submission on Implementing Reforms to the Notification and Assessment Scheme (NICNAS) – Consultation Paper 4

Contact for recipient:

National Industrial Chemicals Notification
and Assessment Scheme (NICNAS)

E: NICNAS.reforms@nicnas.gov.au

Contact for PHAA:

Michael Moore – Chief Executive Officer

A: 20 Napier Close, Deakin ACT 2600

E: phaa@phaa.net.au T: (02) 6285 2373

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Introduction

The Public Health Association of Australia

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

Vision for a healthy population

The PHAA has a vision for a healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and healthy environment, improving and promoting health for all.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Health Equity

As outlined in the Public Health Association of Australia's objectives:

Health is a human right, a vital resource for everyday life, and a key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions of society that underpin people's health. The health status of all people is impacted by the social, political, and environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease.

The PHAA notes that:

- Health inequity differs from health inequality. A health inequality arises when two or more groups are compared on some aspect of health and found to differ. Whether this inequality (disparity) is inequitable, however, requires a judgement (based on a concept of social justice) that the inequality is unfair and/or unjust and/or avoidable. Inequity is a political concept while inequality refers to measurable differences between (or among, or within) groups.¹
- Health inequity occurs as a result of unfair, unjust social treatment – by governments, organisations and people,² resulting in macro politico-economic structures and policies that create living and working conditions that are harmful to health, distribute essential health and other public services unequally and unfairly, preventing some communities and people from participating fully in the cultural, social or community life of society.

Preamble

The PHAA has commented on the three previous NICNAS Consultation Papers and welcomes the opportunity to comment on this fourth Consultation Paper on the Implementation of Reforms to the National Industrial Chemicals Notification and Assessment Scheme. It is noted that this paper outlines the overarching framework for the reforms that is proposed to be set out in new legislation.

The PHAA is pleased to have representation on the NICNAS Strategic Consultative Committee, and on the previous NICNAS Community Consultation Committee, and welcomes the opportunity to be informed about and comment on the regulatory procedures for industrial chemicals in Australia.

The manufacture and usage of chemicals underwent massive expansion post World War II, as part of development, and reliance continues to grow strongly among both the developed and developing nations. Chemical regulation was not introduced around the world until about 1990. Regulation arose in response to community outrage at the widespread multi-generational harm to human health and environmental contamination from laissez-faire chemical use and release into the environment. This relatively late introduction of regulation to assess short term and cumulative exposure risks to human health and the environment presented a back log of unassessed chemicals.

However, by 2016, 85% of chemicals listed on AICS had still not undergone assessment for harm to human health or the environment. Progress has been slow and a clear need exists for this to occur at an accelerated rate. Work commenced by NICNAS on these unassessed chemicals through its Inventory Multi-Tiered Assessment and Prioritisation (IMAP) Program needs to continue as an urgent priority.

The PHAA is supportive of reforms that sensibly refocus regulation to prioritise areas of greatest risk, and ease unnecessary regulatory burden on industry, in order to assist Australian productivity where safety is not comprised. However, PHAA cannot support reforms that erode the capacity of NICNAS to perform its key role of “regulating to protect human health and the environment. Furthermore, prioritising “easing regulation for industry” over “protecting the Australian people and the environment” runs counter to the objects of the Industrial Chemicals (Notification and Assessment) Act, and the justified expectations of the Australian people.

Chemical regulation is one plank within the health protection responsibilities of government. It is important to recognise that health protection differs markedly from health service provision. One key difference is that service provision has clear metrics to indicate performance, such as number of appendectomies performed. When fully functional, health protection successfully prevents ill health, yet non-occurring cases, that is, case prevention is difficult to measure. This ‘lack of evidence of benefit’ can be misinterpreted as a lack of need for regulation or health protection. Indeed this argument is customarily presented by the regulated when arguing for easing of regulation. However, evidence does exist. With respect to environmental protection, and effective chemical regulation, a comparison of the statistics of cases occurring in unregulated societies, against cases among well-regulated societies provides clear evidence of the need for effective regulation.

Australian manufacturers, importers and users of industrial chemicals require clear guidelines for the use of chemicals, and the role of regulation is to ensure that chemicals available and used in Australia are managed in safe conditions for the environment and the whole population, including workers exposed to industrial chemicals.

As part of the 2015 Federal Budget, the Australian Government announced the implementation of reforms to the notification and assessment of industrial chemicals. The reforms, which focus regulatory effort on higher risk chemicals and continue the protection of human health and the environment, deliver a reduction of approximately \$23 million per annum in the burden of regulation on industry.

As the NICNAS regulators develop new guidelines for regulation of industrial chemicals as part of a reform agenda to reduce the regulatory burden on industry, the PHAA and the Australian public need to be assured that the safety of Australians and the environment is fully protected. Reduction in regulatory reporting requirements for industry should not result in reduced fees for NICNAS. Reduced funding for NICNAS activities will diminish its capacity for regulatory oversight, including proposed post-market audit and monitoring for those industrial chemicals which would be exempted from reporting when introduced into Australia under current reform proposals.

Key functional activities that are performed routinely in other countries are lacking in Australia. The PHAA, in representing the interests of public health in Australia, strongly urges that any savings be rechannelled into human bio-monitoring programs.

Comments on Consultation Paper 4

In this submission, the PHAA responds to those matters of continuing concern to community organisations, namely that the NICNAS reforms to reduce the regulatory burden on industry do not erode protections for human health and the environment.

The consultation processes, including six public workshops, have been useful for understanding the proposed reforms. However, as noted by NICNAS, “there are some aspects of the reforms that are contentious and for which there is an absence of agreement across stakeholder groups.”

Categorisation of new chemicals – Exempted Chemicals

Part 1 of Consultation Paper 4 includes a summary of some of the key differences between the current regulatory arrangements for the introduction of industrial chemicals and the proposed new arrangements. However, PHAA and other community groups remain concerned that the proposed new category for Exempted Chemicals will result in a large number of new chemicals being introduced into Australia without prior NICNAS pre-market assessment.

The estimated 70% decrease in the number of chemicals in this Exempted Category, would be a result of self-assessment by industry as low-risk. This may contribute to reducing the regulatory burden on industry by about \$23 million annually, but it is at an increased risk to the health of people and the environment. It is not sufficient that the only compliance requirement is an annual declaration with no reporting on the volume or identity of the chemical to be imported or manufactured in Australia.

As noted previously, PHAA believes unacceptable risks will be introduced in a system whereby regulation of the Exempted Class of chemicals occurs via industry decisions on chemical risk classification, driving a post-entry audit and penalty system, when resources are not set aside specifically for the audits of this class of chemicals. There needs to be a system of convenient online notification to NICNAS for the introduction of industry self-categorised Exempted Chemicals, which requires the importer or manufacturer to acknowledge that severe penalties exist for any wrongful misclassification, misreporting, importation or manufacture of Exempted Chemicals. In addition, severe penalties need to be in place for importers or manufacturers of Exempted Chemicals to discourage illegal import or manufacture of Exempted Chemicals. There should be an annual quota for audits of Exempted Chemicals with dedicated resources to achieve the quota and annual reporting. Pre-warning of industry of forthcoming audits has merit in inducing compliance. However, these would need to be reinforced by surprise audits, sufficient in frequency to discourage gaming the system.

PHAA does not support the view expressed in some submissions that industrial chemicals categorised as non-hazardous should be exempt from the NICNAS frameworks. This could lead to misclassification and insufficient incentive for introducers to collect the information on a chemical's risks to people or the environment. Furthermore, many examples exist whereby chemicals, once thought to be non-hazardous, are later re-categorised as harmful. Absence of routinely data of chemical volumes, usage and location would negate any meaningful subsequent assessment of human risk.

NICNAS does require all introducers to be registered, and therefore subject to audit for compliance, but the PHAA and other community groups are not convinced that this provides sufficient confidence for the community when there is no public listing for all chemicals introduced or in use in Australia.

A further concern is the potential for misclassification. Absence of reporting would reduce NICNAS' capacity to conduct audits to assure accuracy of reporting and decision making to NOT report. Under a scenario of reduced funding, this can be expected to move from the realm of likelihood to certainty. The PHAA regards such erosion of regulatory oversight to be inconsistent with health protection, and therefore totally unacceptable.

The Australian Inventory of Chemical Substances – 30,000 untested chemicals

It is noted that the proposed NICNAS definition for new industrial chemicals introduced into Australia does not include the many chemicals already listed on the Australian Inventory of Chemical Substances (AICS). However, the vast majority of chemicals listed on AICS have still not undergone risk assessment for harm to human health or the environment.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) program, which community and environment groups got behind as an effective method to fast-track the assessment of the 85% of unassessed chemicals on AICS is not mentioned in the Consultation Paper. It is noted that a progress report at the last NICNAS Strategic Consultative Committee meeting on 19 May 2016 described the completion of risk assessments for the first small group of chemicals on schedule, with a very large number still to be prioritised for assessment.

Polymers

The NICNAS proposal to include polymers in the new chemicals framework, rather than exempting them in a similar way to the EU-REACH program, is supported. This is sensible at a time when the European Commission is in the process of exploring options for the registration of polymers as part of a review of REACH. There are risks that some low molecular weight polymers have the potential for absorption into the body, and many polymers that contain perfluorinated carbon chains could breakdown to perfluorinated chemicals which could persist in the environment, may bioaccumulate, or may be toxic.

NICNAS outlines some definitions to reduce confusion about release volumes for treated or untreated chemicals into the environment. PHAA will follow with interest this important issue to ensure that the NICNAS reforms, in conjunction with the National Standard being established by the Department of the Environment for environmental risk management of industrial chemicals, to ensure that there is no risk to the waterways and their ecosystems from runoff of harmful industrial chemicals or their by-products.

PHAA also notes the lack of human biomonitoring within Australia, whereas chemical body burden monitoring programs are routine in many countries including the USA, Canada, and Europe. Many other countries, such as Russia, China, India, Taiwan, Turkey, and French West Indies similarly test the chemical loading among their population. This is the ultimate test of efficacy of a regulatory framework, i.e. human biomonitoring is the gold standard of evaluation. Regulation "to protect human health and the environment" from the hazards of chemical exposure requires a metric to evaluate performance against this primary objective. No valid case can be presented that argues for lessening health protective regulation

when there is no data to indicate efficacy or otherwise of the existing framework. Any costs savings arising from these reforms must be re-allocated to establish a population wide annual system of human biomonitoring for chemical burden, reinforced by periodic rotating testing of high risk groups, such as children, workers, regional populations. NICNAS cannot claim world standard chemical regulation when there is no test of efficacy. The PHAA believe this situation untenable, and places an unacceptable risk on the Australian public. The PHAA therefore urges biomonitoring to be instated with a perpetual funding stream, such as those operating in the USA and many other countries.

Use of international information and assessments

Recognition of approvals by comparable regulators in other countries is supported as a practical approach to reducing the regulatory burden on Australian importers and manufacturers of chemicals. Bans on particular chemicals by regulators in other countries need to be scrutinised for the reasons which resulted in bans and how these conditions relate to the use of these chemicals in Australia. This needs to be undertaken in a timelier manner than currently happens.

The PHAA would support some publication of assessment information, similar to the short summaries published by Canada. The PHAA agrees with NICNAS that the USA model of not publishing any information about assessments is not appropriate for Australia, and would erode public confidence in the system.

The PHAA notes that NICNAS does not consider that the risk assessments conducted by the US EPA meet the current criteria for regulators set by the Health Portfolio, primarily due to transparency issues since the US EPA does not publish its risk assessment reports. However, NICNAS is encouraged to continue with its efforts through its current bilateral relationship with the US EPA to explore to what extent assessment materials from the US EPA could be adopted by NICNAS in the future.

Nanomaterials

The PHAA believes that the introduction volumes up to 100kg for nanomaterials used in Research and Development (R&D) for classification as Exempted Chemicals needs to be reduced. It is not appropriate for such large quantities of these materials, to be introduced, even for R&D, without the knowledge of NICNAS, given the limited understanding of the risks they may pose to people and the environment.

Monitoring and enforcement

The Government decision (informed by the Regulation Impact Statement) acknowledged that NICNAS' current monitoring and enforcement powers are not suitable for the increased focus on post-market monitoring as planned in the reforms. In addition, NICNAS notes a number of current common areas of non-compliance.

It is therefore critical that the NICNAS reforms provide confidence for the communities that there are no increased risks to human health and the environment from inadequate funds for post-market entry audit, monitoring and enforcement actions. It is noted that NICNAS will be seeking independent advice on the design of the future auditing framework, and that NICNAS will engage with industry and community representatives, later in 2016, to develop its auditing framework.

NICNAS notes that planned new contemporary compliance powers will enable NICNAS to deal with serious non-compliance in situations where informal approaches seeking voluntary compliance are ineffective or fail to meet industry and community expectations. Community stakeholders, including the PHAA, will be interested in continued engagement in the consultation process in the development of Cost Recovery Implementation Statements (CRIS) to ensure that sufficient resources will be allocated to ensure effective compliance monitoring and audits for all classes of chemicals, and Exempted Chemicals in particular. The PHAA remains concerned that in the absence of information about all industrial chemicals being introduced into Australia, that NICNAS is unlikely to become aware of breaches.

Confidential Business Information – New Chemicals

NICNAS notes that there has been divergent stakeholder feedback on the proposed system of masked names for protecting chemical identity. In particular, community stakeholders have expressed concern at the lack of transparency that masking may provide, while many industry stakeholders have expressed concern that masked names would not adequately protect chemical identity. The PHAA supports the NICNAS proposal that the introducer could propose a name (a chemical name, not a trade name) that delivers a sufficient level of CBI protection, but enables the implementation of appropriate risk management action

In conclusion, the PHAA is pleased to provide these comments in relation to this major reform for the regulation of industrial chemicals in Australia because of the importance of ensuring the safety of the whole community and the environment, including workers exposed to industrial chemicals.

Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.



Michael Moore

BA, Dip Ed, MPH
Chief Executive Officer
Public Health Association of Australia



Joe Hlubucek

PhD, FRACI
PHAA Representative on
NICNAS Strategic Consultative Committee



Liz Hanna

RN, BA, MPH, PhD, FACN, FPHAA
Past PHAA Representative on
NICNAS Community Engagement Forum

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