



Public Health Association
AUSTRALIA

Public Health Association of Australia submission on Implementing Reforms to the Notification and Assessment Scheme (NICNAS) – Consultation Paper 2

Contact for recipient:

National Industrial Chemicals Notification
and Assessment Scheme (NICNAS) –
Consultation Paper 2

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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

PHAA welcomes the opportunity to comment on this second Consultation Paper on the Implementation of Reforms to the National Industrial Chemicals Notification and Assessment Scheme.

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 for safety presented a back log of unassessed chemicals.

However, by 2016, 85% of chemicals listed on AICS have 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.

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. 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 recognize 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 are difficult to measure. This ‘lack of evidence of benefit’ can be interpreted 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 done so 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 are fully protected. Reduction in regulatory burden for industry cannot translate to loss of income if that diminishes capacity of NICNAS to provide health and environmental protection.

Key outcomes of Consultation Paper 1

The summary of key outcomes from the responses to Consultation Paper 1 was useful. In addition the public workshops provided a very good opportunity to review the proposed NICNAS reforms. Protection from harmful chemical exposure is an area of high public concern, and hence alterations to regulation that impinge upon health protection is ‘everybody’s concern’. The PHAA will encourage broader participation in future workshops by public health and environmental organisations through its networks, and this will be assisted with early advice on the dates for the next public workshops, including any dedicated community workshops.

Part B opens with the statement “In summary, stakeholders generally supported the direction of the reforms and the move to a more proportionate risk-based approach relative to the current approach”. This is misleading, and implies broad scale support from all sectors. Whilst it may accurately reflect the total number of submissions received, our discussions with the community sector revealed they were uniformly critical. PHAA respectfully requests that such divergence of views be reflected in all future statements.

International assessments PHAA endorses approaches that accelerate the assessment process through the backlog of unassessed chemicals, when these are undertaken via scientifically valid methods, and that adequately address safety. Europe and Canada have world class systems. Political interference in the processes in the United States has been widely criticised by scientists which subsequently casts doubt on theirs. It is vital that different volumes or uses within Australia, and environmental fate are considered when incorporating international assessments. For example, low flow rates in Australian waterways are conducive to concentration.

The outcomes from the Consultation Paper 2 also noted that stakeholders sought further information on a number of matters, including NICNAS’ proposed approach to audit, monitoring and compliance. These are matters of continuing concern to community organisations, and it is hoped that there can be more consideration to these matters before Consultation Paper 3, which is when NICNAS advises that they will be addressed. An extensive global record exists of environmental contamination and resultant persistent health burden arising due absence or shortfall in regulation and monitoring. Such events substantially reduced with the introduction of regulation alongside efforts to ensure compliance, which clearly testifies to their efficacy and health importance. PHAA is keen to see improvements in monitoring and compliance.

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. 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.

Key Changes since Consultation Paper 1

It is noted that NICNAS proposes to introduce a simple automated online declaration system for Reported Chemicals. However, PHAA is interested in such a process being adapted to include notification of the introduction of the large number of Exempted Chemicals, which under the proposed NICNAS regulatory reforms would not require importers or users to notify NICNAS.

The realm of toxicology and understanding of impacts of chemical exposures upon human health and key ecological systems that support human health, such as food and water supplies, is a dynamic science. The toxicological literature is replete with examples of chemicals and agents that once thought safe, are subsequently shown to have deleterious effects, often very serious in nature. The PHAA is concerned that systems are being proposed that would deny the regulatory agency any knowledge of chemical manufacture, storage, and usage, or of the volumes involved and their location. A system that limits the database to currently known harmful chemicals actively prevents examination at a later date of exposures and effects. From a health perspective, this is a dangerous precinct. Such erosion of health protection and Australia's capacity to examine exposures and potential links with health harm is unacceptable to PHAA.

The impost on industry in providing information on chemicals, the volumes and location of manufacture or distribution would be minimal, given that industry keeps records of its inputs and outputs as part of routine financial management systems.

Proposals to reduce income from the industry will inevitably hamper the capacity of NICNAS to conduct the assessments, or provide effective regulation. The PHAA urges NICNAS to uphold its obligations to protect human health and the environment, and instead increase its capacity. A minimalist approach that reduces regulation purely to appease industry, but blind to efficacy fails to provide safety assurance or meet the standards set out in the Act, and expected by the Australian population.

Evidence of prioritising the wishes of industry over public health permeate this document, which is deeply concerning to the PHAA. For example, in section E page 20 *“An absence of data does not necessarily indicate a specific hazard”*. Whereas this statement is true, the absence of the corollary statement *“An absence of data does not necessarily indicate absence of hazard”*, serves to support an argument that absence of data is an acceptable situation, warranting no further action. Harm may not be assumed by the lack of data, but lack of data offers zero assurance of safety.

Impact of the Reforms and Changes in Terminology

PHAA supports moves that encourage the shift to safer and greener chemistry. However, the claim that newer and safer chemicals will be introduced by the regulatory reforms is questioned. In the absence of monitoring and evidence, it is a claim that cannot be substantiated, and until such time as that evidence is delivered, the claim has no bearing.

A focus on the more hazardous classes for Reported and Assessed Chemicals is desirable, but any limitation in resources for NICNAS, would result in limited resources being available for post-entry compliance monitoring for the larger new category of Exempted Chemicals. A \$23 million per annum reduction in regulatory burden to industry is likely to result in significant fall in NICNAS revenue stream. The latter category of chemicals, under the proposed reforms, could be introduced into Australia by importer or manufacturer self-assessment without any NICNAS notification. There needs to be some form of convenient online notification to NICNAS for the introduction of any Exempted Chemicals, which requires the importer or manufacturer to acknowledge that severe penalties exist for any wrongful import 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.

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.

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.

Part G Exempted Chemicals (previously Class 1) and Reported Chemicals (previously Class 2)

Concerns remain about the large number of exempted chemicals which will be imported under the reform agenda without any notification to NICNAS. The simple online declaration envisaged for Reported Chemicals, as part of the new information system, should also be applied to Exempted Chemicals to provide some record for introduction of these chemicals into Australia.

It may not be sufficient to regulate Exempted Chemicals by a post-entry audit and penalty system, particularly if dedicated resources are not set aside for the audits of this class of chemicals. In addition to ensuring that the penalties are significant enough to be effective deterrents for incorrect or misuse of self-accreditation, there should be an annual quota for audits of Exempted Chemicals with dedicated resources to achieve the quota and annual reporting.

Audit and monitoring

NICNAS notes that 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 will be interested in being consulted 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, including Exempted Chemicals. PHAA is concerned that in the absence of information, NICNAS is unlikely to become aware of breaches.

Chemical regulation, introduced around the world as late as about 1990, arose in response to widespread multi-generational harm to human health and the also to the environment from laissez-faire chemical use and release into the environment. Introduction of regulation to assess for safety presented a back log of unassessed chemicals. However, by 2016, 85% of chemicals listed on AICS have still not undergone assessment for harm to human health or the environment. Progress has been slow and a clear need exists or this to occur at an accelerated rates. A tick-the-box solution fails to provided safety assurance or meet the standards set out in the Act, and expected by the Australian population. Proposals to reduce the capacity of NICNAS to conduct the assessments, in collaboration with our international partners, by willingly reducing income from the industry, will inevitably hamper the capacity of NICAS to offer effective regulation. The PHAA urges NICNAS to uphold its obligations to protect human health and the environment, and instead increase its capacity.

The *Inventory Multi-tiered Assessment and Prioritization* (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 also goes unmentioned in the Consultation Paper. Has it been successful? Why does it need to change?

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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.



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References

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