



Public Health Association
AUSTRALIA

**Public Health Association of Australia
submission to the Senate Committee on
Community Affairs, Legislative Committee
Inquiry into the Industrial Chemicals Bill 2017
and related Bills**

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Senate Committee on Community Affairs,
Legislative Committee, Inquiry into the
Industrial Chemicals Bill 2017 and related
Bills

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Introduction

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia. The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups (SIGs) and members. The SIGs include the Ecology and Environment SIG which as followed the regulatory reform moves by the Government to reduce the regulatory burden on industry by reducing the reporting requirements.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, 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. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a 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.

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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.

PHAA recognises the foundational role of the Earth's ecosystems to human civilisation, prosperity, health and wellbeing, the nature of humanity's inextricable relationships with the ecosystem of which we are a part. PHAA recognises, in this context, that these ecological determinants of health (an Eco-social viewpoint) are entwined with health and wellbeing along with socially determined influences. PHAA will act and call for action for the promotion and protection of the health of the ecosystems in a concerted manner in its policy development and implementation.

Preamble

The PHAA welcomes this opportunity to outline its concerns to the Senate about the direction of the proposed regulatory reforms outlined in the Industrial Chemicals Bill 2017. The proposed reforms are aimed at reducing the regulatory burden on industry by reducing the industry reporting requirements for the introduction of new chemicals into Australia – but at a higher risk to human health and the environment.

The PHAA is pleased to have representation on the National Industrial Chemicals Notification and Assessment Scheme (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.

However, the PHAA wishes to record its concern at the very short notice from the Committee of three working days for submissions, with a deadline of Monday, 12 June 2017, which is a public holiday in most jurisdictions. Furthermore, the invitation for submissions states that the Committee will consider all submissions, and may invite individuals and organisations to give evidence at public hearings, but it is unclear how much serious deliberation is possible when the Committee plans to report to the House on 13 June 2017.

The PHAA and other community groups have raised their concerns in responses to the four previous NICNAS Reform Consultation Papers and is disappointed that the proposed reforms will now allow many new chemicals to be imported into or manufactured in Australia without any Government or public record of these introduced chemicals.

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 the Australian Inventory of Chemical Substances (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.

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 compromised. However, PHAA cannot support reforms in the proposed Australian Industrial Chemicals Introduction Scheme (AICIS) that erode the capacity of current regulations in the NICNAS to perform the Government's 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 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

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misinterpreted as a lack of need for regulation or health protection. Indeed this argument is customarily presented by the regulated industry 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.

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, deliver a reduction of approximately \$23 million per annum in the burden of regulation on industry, but reduce the Government's oversight for the protection of human health and the environment.

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.

In addition, it is essential that there is a Government or public record for all industrial chemicals introduced into Australia, a requirement which will no longer apply if the Senate approves the Industrial Chemicals Bill 2017 in its current form.

As the Government prepares to introduce 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.

In this submission, the PHAA responds to those matters of continuing concern to community organisations, namely that the AICIS 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."

PHAA Response to Inquiry

Categorisation of new chemicals – Exempted Chemicals

In his second reading of the Industrial Chemicals Bill 2017 on 1 June 2017 in the House of Representatives,³ the Assistant Minister for Health stated that "by enabling industry to self-assess lower-risk chemicals, this reduces the number of chemicals assessed by the regulator by more than 70 per cent—thereby reducing costs to industry, and also enabling the regulator to focus its efforts on higher-risk chemicals".

The PHAA and other community groups remain very concerned that the proposed new category for Exempted Chemicals will result in a large number of new chemicals being introduced into Australia without prior notification to the AICIS Regulator and without entry into any Government or public record. Clear evidence now implicates exposures to industrial and agricultural chemicals in developmental problems and other illnesses, including congenital malformations, cancers, diabetes, allergenicity, generalised immune disorders, asthma, neurological and behavioural conditions, endocrine disruption, and, perhaps, obesity and autism.⁴

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

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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, the 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, requiring 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 prior online notification to the AICIS Regulator for the introduction of industry self-categorised Exempted Chemicals, which should be straightforward with the improved IT systems being developed for AICIS.

In addition, severe penalties need to be in place to discourage illegal import or manufacture of self-assessed Exempted Chemicals, particularly with the increase in import of industrial chemicals via the internet. Importers and manufacturers of industrial chemicals should also be required at the time of annual registration to acknowledge that severe penalties exist for any wrongful misclassification or misreporting for importation 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, this needs to be reinforced by surprise audits, sufficient in frequency to discourage gaming the system.

The PHAA does not support the view expressed in some submissions that industrial chemicals categorised as non-hazardous should be exempt from the AICIS 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 currently requires all introducers to be registered (for payment of fees), and therefore liable 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 will reduce AICIS' capacity to conduct audits to assure accuracy of reporting and decision making to avoid reporting. 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.

It is important to note the experiences and consequences with under reporting in the USA for industrial chemicals in a reduced reporting environment for new chemicals under the US EPA and its Toxic Substances Control Act (TSCA). Under the TSCA, the EPA is mandated to use the least burdensome method to reduce chemical risk to reasonable levels, taking into account the benefits provided. However, as a result of the limitations of the TSCA, US States have introduced their own legislation leading to 71 specific chemical regulation laws being passed in 18 different states since 2003.⁵

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

It is noted that the proposed AICIS 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.

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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 needs to be accelerated with increased funding from industry. 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.

Lack of human biomonitoring

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 re-allocated to establishing 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. AICIS could not 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.

Nanomaterials and Polymers

There are many new classes of chemicals, including nanomaterials and polymers, which deserve special regulatory consideration for health risks to humans, animals and the environment, and should not be categorised as Exempted Chemicals. Nanomaterials are designed to penetrate the skin and even deliver active biomolecules to intracellular sites, and none of these chemicals should be categorised as Exempted Chemicals.

Many polymers should not be categorised as Exempted Chemicals. 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.

The PHAA believes that the introduction volumes up to 100kg for nanomaterials used in 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 the AICIS Regulator, given the limited understanding of the risks they may pose to people and the environment.

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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.

This is not the situation in which Exempted Chemicals should be introduced by self-assessment and then have no Government or public record of these industrial chemicals introduced into Australia.

It is therefore critical that the AICIS 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.

PHAA notes that planned new contemporary compliance powers would enable AICIS 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 AICIS is unlikely to become aware of breaches in a timely manner.

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.

The PHAA and other community groups are particularly concerned about the proposed reduction in regulatory oversight by AICIS for the new category of Exempted Chemicals. It is unacceptable that new chemicals can be introduced into Australia on the basis of self-assessment by importers or manufacturers without any prior notification to AICIS and no listing of such chemicals on a Government or public record.

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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