



THE HON MARK COULTON MP

Minister for Regional Health, Regional Communications and Local Government
Federal Member for Parkes

Ref No: MS20-000637

Dr Brian Richards
Executive Director
Australian Industrial Chemicals Introduction Scheme
GPO Box 58
SYDNEY NSW 2001

8 JUL 2020

Dear Dr Richards

I am writing to express my appreciation of the valuable and important work undertaken by the Australian Industrial Chemicals Introduction Scheme (AICIS), to aid in the protection of human health and the environment, and to outline my expectations for industrial chemicals regulation, with a focus on the next 12 months. This Statement of Expectations (Statement) will assist with the Australian Government's commitment to effective governance and performance of the AICIS, guided by the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

I note the new legislation, the *Industrial Chemicals Act 2019* (IC Act) supersedes the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) to create the new Scheme, the AICIS, for the importation and manufacture of industrial chemicals in Australia (that commenced on 1 July 2020).

INTRODUCTION

The Government recognises and respects the independence of the Executive Director of AICIS and your responsibility for regulation of a national scheme for the introduction of industrial chemicals in Australia, as provided by the IC Act. To maintain confidence in the regulatory framework, it is imperative that the AICIS acts, and is perceived to act independently.

Under the IC Act, the AICIS carries out a number of other functions in relation to industrial chemicals regulation, which include the provision of advice and ensuring Australia's obligations under international agreements are met. The AICIS is expected to provide these functions with the highest level of integrity and based on a firm understanding of industrial chemicals and risks. The Government expects that the AICIS should maintain a high level of awareness of the Government's health, industry and environmental policy objectives and respond effectively to Government policy directions and objectives. The Government also expects that the AICIS, in fulfilling its role, will maintain productive working relationships with other relevant jurisdictional and Commonwealth regulators and relevant international bodies.

VISION

I would like to emphasise the objectives of the AICIS as outlined in the IC Act, which are to:

- provide for a national scheme to regulate the introduction of industrial chemicals in Australia
- aid in the protection of human health and the environment including through the:
 - regulation of the introduction of industrial chemicals
 - assessment and evaluation of the introduction and use of certain industrial chemicals
 - provision of information and recommendations about managing the risks arising from the introduction and use of industrial chemicals.
- provide for the collection and publication of information and statistics relating to industrial chemicals
- give effect to Australia's obligations under international agreements and arrangements relating to the regulation of industrial chemicals.

The rationale for the Government reforming industrial chemicals regulation is to leverage the fullest possible benefits that can be derived from making regulatory effort more proportionate to risk. The AICIS will promote safer innovation by encouraging the introduction of lower risk chemicals and will continue to protect the Australian people and the environment from harmful effects of industrial chemicals, as reflected clearly in the legislation.

This outline should also guide longer-term planning for the AICIS in fulfilling its obligations and functions outlined in the IC Act, including advice and implementation of Government priorities for industrial chemicals regulation.

PRIORITIES

The Government expects that you and the AICIS continue to aid in the protection of human health and the environment through regulation, monitoring, and risk assessment in relation to the introduction and use of industrial chemicals, through the following priorities.

Effective transition from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to the AICIS

On 1 July 2020, the AICIS replaced NICNAS as the national regulator for the importation and manufacture of industrial chemicals in Australia. I expect the AICIS to work within the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (and associated Ministerial Rules) which provide a framework to ensure the effective transition of the regulation of industrial chemicals from the NICNAS to the AICIS. I also expect the AICIS to work collaboratively with the Commonwealth Health Portfolio and other Commonwealth stakeholders, and for all affected stakeholders to experience a well-managed transition.

Effective implementation of the new Scheme

I expect the new Scheme to maintain current levels of health and environmental protections while reducing pre-market assessment effort through:

- the publication of information that is more meaningful for industry and the public about the effects of industrial chemicals on human health and the environment.
- appropriate confidentiality for business information while considering the public interest in accessing this information.
- consultation with risk managers when considering taking certain regulatory actions.
- appropriate use of available monitoring and enforcement powers, leading to more effective management of any non-compliance.

In addition, in recognition of the newness of the Scheme, I expect the AICIS to monitor and review implementation of the cost recovery model. AICIS should review the cost model and the Cost Recovery Implementation Statement through annual reviews that consider the data collected and stakeholder feedback received. This review should also consider the eight tier registration charging model to confirm the relevance of the thresholds and whether the introduction value remains to be the most appropriate proxy for regulatory effort and therefore, charging.

Implementation of the ban on cosmetic testing on animals

The commencement of the AICIS delivers components of the ban on cosmetic testing on animals. I expect the AICIS to implement the ban, as far as is possible, through these components:

- adherence to Ministerial Rules which restrict the use of new animal test data to support certain chemical introductions with a view to promote the development and uptake of alternative test methods
- publication of statistics on the use of animal test data.

International harmonisation

The new Scheme encourages greater harmonisation with international approaches to the regulation of industrial chemicals and provides for the use of components of assessments of comparable international regulators in the AICIS risk assessments. I expect the AICIS to promote the international harmonisation of regulatory controls or standards (meeting the Health Minister's criteria) for industrial chemicals through appropriate engagement with relevant international organisations and government agencies.

RELATIONSHIP WITH MINISTER AND PORTFOLIO

The AICIS plays an essential role in ensuring that I, as the Minister for Regional Health, Regional Communications and Local Government, and the Government, are well placed to respond promptly to issues that may arise in industrial chemicals regulation.

You, as Executive Director of the AICIS should, therefore, provide Government with accurate and timely advice on significant issues in the Scheme's core area of business. Significant issues might include: matters for which the Government is likely to be accountable in Parliament; and important operational or budgetary issues. I would also expect you to work closely with the Department of Health in contributing to ongoing policy advice and ideas to strengthen our vision for industrial chemicals in Australia.

In this context, I am looking forward to maintaining my close working relationship with the AICIS and the Office of the Chief Medical Officer. I request that I, and the Department, are consulted early in the development process for future work, and I will ensure you are fully informed of the Government's policy direction as specific initiatives and strategies are considered. The Government expects that the AICIS and the Office of Health Protection continue to maintain a close working relationship.

ORGANISATIONAL GOVERNANCE AND FINANCIAL MANAGEMENT

I expect the AICIS to continue to comply with the principles of the Commonwealth Resource Management Framework as specified in the PGPA Act, and to give effect to the governance, performance and accountability requirements covered by the PGPA Act applicable to a non-corporate entity. Furthermore, I expect that the AICIS maintains the capacity to be flexible and responsive to emerging priorities and issues which might arise throughout the year.

REGULATORY FRAMEWORK

As the Executive Director of the AICIS, I expect you will exercise your regulatory functions appropriately and according to the IC Act. In addition I would ask the Executive Director also act in accordance with Government policies to minimise regulatory burden and maximise the clarity and transparency of your operations. I understand that a key mechanism to achieve this in relation to the use of industrial chemicals will be through continuing to assess the risks and providing information to promote their safe use.

TRANSPARENCY AND ACCOUNTABILITY

The AICIS is accountable to me, as the Minister for Regional Health, Regional Communications and Local Government, and to the Parliament.

I expect the AICIS to prepare a report on the operation of the IC Act (as per s179 of the IC Act) for inclusion in the Department's Annual Report (in accordance with the PGPA Act). A copy of the Annual Report is provided to me, as the responsible portfolio Minister, and to Senator the Hon Mathias Cormann, the Minister for Finance.

I would appreciate your response to this letter in the form of a Statement of Intent within three months of receiving this Statement, outlining how the AICIS proposes to meet the expectations outlined herein, and ensure that the Government's priorities are reflected in AICIS' strategic and operational plans. The AICIS has a leadership role in advancing the Government's industrial chemicals policy agenda and I am keen to understand how the AICIS' new strategic direction will deliver the outcomes of industrial chemicals regulation.

To enable greater transparency and accountability, information in this letter along with your response should be published and made publically available on your website in due course.

Yours sincerely



Mark Coulton

cc: The Hon Greg Hunt MP, Minister for Health