



Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill 2007

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Law and Bills Digest Section

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Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill 2007

Date introduced: 13 June 2007

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Sections 1 to 3 commence on Royal Assent. Schedules 1 and 2 (containing the main operative provisions) commence 28 days after the Act receives the Royal Assent.

Purpose

The purpose of the Bill is to amend the *Industrial Chemicals (Notification and Assessment) Act 1989* to:

- provide legislative underpinning for recent reforms to the regulation of cosmetics in Australia, which currently only exist on a limited, interim, administrative basis. The reforms concern chemicals in cosmetics which are considered to be of low regulatory concern.
- enable the Minister to make standards by legislative instrument, for cosmetic products as a whole that are imported into, or manufactured in, Australia.
- include a criminal offence for importing into, or manufacturing in, Australia a cosmetic that is subject to the standard and does not meet the standard.
- make minor changes to the Act of a technical or uncontroversial nature, so as to improve the clarity, increase consistency, and address minor technical anomalies or unintended effects of the legislation.

Background

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) establishes a system of notification and assessment of industrial chemicals to protect health, safety and the environment and to provide for registration of people or companies proposing to introduce industrial chemicals into Australia.¹

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) administers the Act and is located within the Commonwealth Department of Health and Ageing. Established in 1990, it sits within the Office of Chemical Safety, which in turn sits within the Therapeutic Goods Administration (TGA) Group of Regulators.² NICNAS

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deals directly with the industry and the public in issuing permits, providing advice, and publishing the Chemical Gazette.

Basis of policy commitment

Review of regulation of cosmetic chemicals

As part of the Government's broader initiatives to reduce regulation, NICNAS established the Low Regulatory Concerns Chemical Taskforce. The Taskforce was enlisted to examine possible reforms to the systems of regulation of chemicals that were deemed to be of 'low regulatory concern'.³ The Taskforce, with the aid of the Cosmetics Implementation Working Group, subsequently released a report in 2005 entitled [*Regulation of Cosmetic Chemicals: Final Report and Recommendations*](#).⁴ The report's recommendation for reforms to cosmetics regulation was endorsed by Government. It was understood that the reforms would be achieved by legislative reform. In addition, a [*Regulatory Impact Statement*](#) was produced.⁵

The Explanatory Memorandum details the major objectives of the agreed reforms suggested by the final report.⁶ One of the primary objectives of the reforms is to clarify the respective roles and responsibilities of NICNAS and TGA in regards to regulation of cosmetic chemicals, with an appropriate apportionment of regulatory effort depending on the chemical's level of risk. The final report explained the relative roles of the organisations:

NICNAS is a chemical entity based notification and risk assessment scheme (as opposed to the TGA that operates a product registration scheme), where all ingredients in a product require assessment if not already entered on the Australian Inventory of Chemical Substances (AICS) (unless subject to exemptions, when various compliance safeguards apply). Where products are reclassified as cosmetics, each individual ingredient not already listed on the AICS will require assessment or transfer onto the inventory through another acceptable mechanism.

Therefore, NICNAS and the TGA, in consultation with all industry stakeholders will establish an appropriate mechanism for the transfer of chemicals not listed on the AICS and currently included in products proposed for reclassification ensuring minimum impact on industry.

Other objectives of the reforms are:⁷

- improved regulation at the interface for identified product types, including changes that could enhance the transparency and useability of existing regulatory documents; and
- specifically addressing issues dealing with antiperspirants, mass-market antidandruff shampoos, moisturisers with SPF, antibacterial skin washes, and anti-acne cleansers.

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Interim measures

In 2006, the NICNAS Cosmetic Guidelines were introduced. The Guidelines, which implement the recommendations of the final report, provide for the current system of regulating cosmetics. However, permits issued under the Guidelines are administrative in nature; no penalties can be imposed for non-compliance.⁸ The current system depends on industry compliance to meet the standards within the Guidelines. Further,

there are some categories of cosmetics (such as skin whitening products and anti-ageing products) that are not subject to the interim arrangements and will not come within the remit of NICNAS until the legislative changes take effect.⁹

The current administrative system of regulation was introduced as an interim measure, to eventually be replaced by a legislative framework. The Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill (“ICAC Bill”) puts forward that framework.

The intended effect of the reforms is to also

increase international harmonisation with Australia’s key trading partners and ensure greater access to the reforms for all relevant cosmetics products (reducing the regulatory burden and costs to industry).¹⁰

Position of significant interest groups/press commentary

On 14 June 2007, the *Sydney Morning Herald* published an article regarding the release of a Federal Government warning about a brand of imported toothpaste which was found to contain a toxic substance. The article was coincidentally released in the same week as the ICAC Bill’s introduction in Parliament. The article reported:

“A spokeswoman for the Department of Health and Ageing said the scheme already had the power to restrict the use of (the toxic substance) in products, but was now considering launching an in-depth review of the chemical to determine whether further regulatory action was needed, either through labelling or restriction on use in products.”¹¹

The article proceeded to outline the proposed new powers of the Government under the ICAC Bill, to set a national standard for cosmetic products.

The Explanatory Memorandum states that the legislative underpinning of the current system is to be supported by all interest groups. NICNAS consulted widely with a broad range of stakeholders, including the cosmetics industry and its industry bodies; government and non-government organisations; and worker and community representatives.¹²

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Financial implications

The Explanatory Memorandum states that the initiatives are cost neutral.¹³

Main provisions

The Explanatory Memorandum provides detailed coverage of the provisions of the Bill. The following analysis summarises the provisions on a general basis.

Schedule 1—Cosmetics

Schedule 1 amends the Act so that it applies to cosmetics, as well as industrial chemicals. These amendments ensure that the Act applies to cosmetics products that have been imported into, or manufactured in, Australia (as well as the basic chemical ingredients used in manufacturing them). The extension of the Act's scope enables NICNAS to easily deal with chemicals that are already contained within finished cosmetic products.

Item 2 proposes amendment to **section 3 'Objects of Act'**. The proposed new section contains an additional object which is to provide for national standards for cosmetics imported into, or manufactured in, Australia and the enforcement of those standards.¹⁴

Item 11 proposes the insertion of **Part 3B 'Standards for cosmetics imported into, or manufactured in, Australia.'** **Proposed section 81** allows the Minister to set national standards for cosmetic products, by legislative instrument. The Explanatory Memorandum states that the NICNAS will make the standard publicly available — this is in addition to registration of the instrument on the Register of Legislative Instrument and publication in the Chemical Gazette.

Enforceability of section 81 is supported by an offence provision (**proposed section 81A**) for non-compliance with the standard, punishable with 120 penalty units - equating to \$66,000 for a corporation. This penalty is comparable in size to an existing penalty for a similar offence of non-compliance in relation to chemicals (section 15A of the Act).

Schedule 2—Other measures

Part 1 of Schedule 2 (**Items 1-9**) amends various sections to replace references to 'calendar year' with '12 month period'. This amendment is to create consistency in drafting throughout the Act and prevent confusion.

Part 2 (Items 10-13) also promotes consistency in drafting, by bringing sections 21ZB and 22O in line with section 21P. All three sections allow permit applicants to request that certain information they provide be treated as 'exempt information' under section 75 of the Act.¹⁵

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Part 3 (Items 14-16) also promotes consistency in drafting, by bringing section 21F in line with similar sections 21SA and 22D. All three sections allow the Director to request further information from an applicant for the purposes of considering an application for a permit.

Item 17 changes references in paragraphs 28(8)(a) and (b) from ‘biopolymer’¹⁶ to ‘polymer’. The Explanatory Memorandum notes that this amendment corrects an unintended exclusion of polymers that are not biopolymers. While it is noted that the provision was not intended to exclude other polymers, the consequences of ‘widening’ the scope of this provision are unclear.

Item 20 repeals section 77 of the Act, that requires a person who introduces a chemical pursuant to an assessment certificate to, within 7 days, give written notice to the Director that they have done so.

The Explanatory Memorandum states that the section is being repealed due to lack of necessity, as compliance with the section is not linked to any NICNAS regulatory activities. It is also noted that there has been ‘limited compliance’ with the section since it was introduced in 1990. The provision does not contain any penalties for non-compliance; it is unclear how instances of non-compliance have been dealt with by the agency to date.

Items 21-27 introduce the concept of ‘chemical name’ in relation to the publication of notices about chemicals. A ‘chemical name’ of a chemical can vary according to the type of chemical (pure vs. unpure). The amendments clarify the source of a chemical name, and allow for its use in various circumstances.

Items 28 – 33 deal with exempt information in relation to annual reporting obligations. The amendments facilitate the confidential treatment of information that is exempt from reporting requirements, for reasons of commercial confidentiality.

Concluding comments

This Bill seeks to enforce a system that has been administratively practiced by NICNAS since early 2006. The amendments to the Act enable the system for regulating cosmetics to be enforced, supporting it with penalties and Ministerial powers to set standards. Legislating these measure will increased certainty for industry and provide clarity about industry obligations, rights and responsibilities under legislation regarding cosmetic chemicals.

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Endnotes

- 1 Peter Prince, Industrial Chemicals (Notification and Assessment) Amendment Bill 2003, *Bills Digest No.167 2002-03*, Parliamentary Library, Canberra, 4 June 2003, at <http://www.aph.gov.au/library/pubs/bd/2002-03/03bd167.htm>, accessed 18 June 2007
- 2 Therapeutic Goods Administration – organisational structure. at <http://www.tga.gov.au/docs/html/orgchart.htm>, accessed 19 June 2007
- 3 Hon Chris Pyne MP, Minister for Ageing, Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill 2007 (Second reading speech), House of Representatives, *Debates*, 13 June 2007.
- 4 http://www.nicnas.gov.au/Cosmetics/Regulation_Cosmetic_Chemicals_Final_Report_PDF.pdf, accessed 18 June 2007.
- 5 http://www.nicnas.gov.au/About_NICNAS/Reforms/LRCC/Regulation_Impact_Statement_PDF.pdf, accessed 20 June 2007.
- 6 Explanatory Memorandum, p. 2.
- 7 *ibid.*
- 8 Hon Chris Pyne, *op. cit.*
- 9 *ibid.*
- 10 *ibid.*
- 11 Kelly Burke, Alert issued over toxic toothpaste, *Sydney Morning Herald*, p. 5.
- 12 Explanatory Memorandum, p. 8.
- 13 *ibid.*, p. 1.
- 14 *ibid.*, p. 11.
- 15 A section 75 exemption allows for information to be exempt from publication, if publication could reasonably be expected to prejudice substantially the commercial interests of the applicant; and if the prejudice outweighs the public interest in the publication of the information.
- 16 A ‘biopolymer’ is any polymeric chemical manufactured by a living organism, as proteins and polysaccharides.

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